UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

INTERNATIONAL DAIRY FOODS ASSOCIATION)))
and)
ORGANIC TRADE ASSOCIATION) CASE NO.: 2:08-CV-628, 629
Plaintiffs,)
v.) Judge: Graham
ROBERT J. BOGGS (solely in his official capacity as Ohio Director of Agriculture)))))
Defendant.	ý) _)

IDFA SUPPLEMENTAL APPENDIX IN SUPPORT OF SUMMARY JUDGMENT

<u>Document</u>	App.III
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IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

International Dairy: Foods Association and Organic Trade: Association,

Plaintiffs, Case No. 2:08-CV-628

2:08-CV-629

vs. Judge Graham

Robert J. Boggs,
Director, Ohio
Department of
Agriculture,:

Defendants. :

DEPOSITION OF ROBERT J. BOGGS

Taken at Schottenstein, Zox & Dunn Co., LPA 250 West Street, 7th Floor Columbus, OH 43215 September 3, 2008, 8:30 a.m.

Spectrum Reporting LLC 333 Stewart Avenue, Columbus, Ohio 43206 614-444-1000 or 800-635-9071 www.spectrumreporting.com

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September 3, 2008

- 1 proceeding?
- 2 A. No.
- 3 Q. Tell me generally about your
- 4 involvement with the dairy labeling rule that is
- 5 at issue in this lawsuit.
- 6 A. I first became aware of the so-called
- 7 rbST issue when the State of Pennsylvania,
- 8 Commissioner Wolf, indicated that he was going to
- 9 revise policy in Pennsylvania regarding labeling
- 10 of rbST in milk.
- That event created a good deal of
- 12 e-mail, telephone, letter writing to the
- 13 department concerning what Ohio was going to do,
- 14 if anything, concerning the labeling of dairy
- milk, dairy products that had or did not have
- 16 rbST.
- 17 Q. When was this?
- 18 A. This was in October of 2007.
- 19 Q. So prior to October of 2007, is it
- 20 correct that you had no awareness of the rbST
- 21 issue, as you put it?
- 22 A. I was aware of the rbST issue in that
- 23 it was a controversial product, but not in regard
- 24 or relationship to any labeling.

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- 1 Q. Were you aware that Monsanto had
- 2 provided information to ODA regarding the science
- 3 behind rbST?
- 4 A. I believe I am aware of that, and we
- 5 also asked Ohio State to provide us -- we were
- 6 concerned, again, about the health impact of rbST.
- We asked a number, and I indicated to the chief
- 8 that we should get as much information from as
- 9 many different sources as we could regarding the
- 10 health implications of rbST.
- 11 Q. When you say "the chief," by the way,
- just to clarify the record, who are you referring
- 13 to?
- 14 A. Chief Jones.
- 15 Q. How would you describe your role versus
- 16 his role in general in connection with the
- 17 establishment of the rule?
- 18 A. First of all, the final decision was
- 19 mine, and I used Chief Jones and our legal people,
- 20 the assistant director especially, to vet all the
- 21 information.
- We went out. We had the first meeting,
- 23 a public meeting in October just within a few days
- 24 after Pennsylvania dealt, had 75 people show up

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- 1 and talk about rbST.
- 2 Then we went to the advisory committee,
- 3 and all this time we're collecting information
- 4 from as many different sources as we can. So
- 5 we're out there getting a lot of information. We
- 6 heard a lot of rumors, a lot of stuff, and I kept
- 7 myself above it all as much as possible. And they
- 8 were the ones collecting the information and
- 9 making recommendations.
- We also brought the governor's office
- into it to inform them of our concerns about
- taking action on this issue to, once again, make
- 13 sure that consumers out there did not have a food
- scare and had the information they needed to make
- 15 good decisions about rbST. But I was not
- personally involved in a lot of these
- 17 conversations and the collection of the
- 18 information. That was reported to me in a
- 19 synthesized way.
- 20 Q. And, finally, on Monsanto, were you
- 21 aware that ODA was in contact with them regarding
- 22 how the rule would be enforced?
- 23 A. No.
- 24 Q. Were you aware, for example, that

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- 1 Chief Jones told Monsanto that the Kroger label
- 2 was out of compliance?
- 3 A. No. I was aware he told Kroger it was
- 4 out of compliance, but nobody else.
- 5 Q. Okay. Now, you called the issue an
- 6 emergency, didn't you?
- 7 A. Uh-huh.
- 8 Q. Why?
- 9 A. As I indicated, there had been a number
- of food scares in the state in 2007. We did not
- 11 want to create any sort of apprehension in the
- 12 marketplace about the safety of milk produced
- 13 either with rbST or without rbST.
- 14 In addition, we wanted to make
- 15 sure this was a new issue to many consumers -
- that they had the most accurate information
- 17 available and complete information available about
- 18 the whole issue.
- To a lesser degree, there were some
- 20 producers that were saying we've got to make
- decisions as to whether or not we're going to
- 22 continue to use Posilac or not. And we had
- 23 processors that are saying we're about ready to
- 24 change our labels. We don't want to spend a lot

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- 1 of money changing labels and not know that the
- 2 department's going to accept them.
- 3 Q. Posilac had been in use since the '90s
- 4 by that point, right?
- 5 A. Uh-huh.
- 6 Q. You knew that, right?
- 7 A. Uh-huh.
- 8 Q. You said yes to those questions, right?
- 9 A. I said yes.
- 10 Q. Okay. Thank you.
- 11 A. Yes.
- 12 Q. And, in fact, during the entire period
- between 19 -- at least 1997 and 2007, during that,
- 14 roughly, ten-year period of Posilac use in the
- 15 industry, there were no Ohio statutes governing
- 16 its use; isn't that correct?
- 17 A. To the best of my knowledge, there were
- 18 no statutes governing its use.
- 19 Q. Well, when you came into office --
- 20 A. Yes.
- 21 Q. -- in January of '07, there was no such
- 22 rule or statute, correct?
- 23 MR. PATTERSON: Objection; calls for a
- 24 legal conclusion. Are you talking about statutes

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- 1 that specifically reference rbST or statutes that
- 2 talk about misleading labels?
- 3 MR. SUNSHINE: Either.
- 4 MR. PATTERSON: I'll object to the
- 5 extent it calls for a legal conclusion. You can
- 6 answer, I guess.
- 7 A. Okay. I was aware that there were
- 8 statutes that deal with misleading labeling, and
- 9 the department has the responsibility to make sure
- 10 that the information on the label is not
- 11 misleading or in error.
- I have no knowledge of any such statute
- 13 or rule regarding rbST.
- 14 Q. Okay. So you knew there were statutes
- saying that you couldn't produce a misleading
- 16 label in general, but you didn't know any that
- 17 referred specifically to rbST?
- 18 A. That is correct.
- 19 Q. Okay. What specifically happened in
- 20 2007 to create this emergency?
- 21 A. I believe I indicated that we received
- 22 a number of e-mails, phone calls, letters. We had
- a public meeting in which 75 people turned out on
- fairly short notice who had very strong points of

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- 1 view on all sides of the issue. And, as I
- 2 indicated, we wanted consumers to be assured that
- 3 the milk they put on their table each day was safe
- 4 and that they had information about it.
- 5 Q. To your knowledge, had ODA taken any
- 6 enforcement actions regarding milk labels from
- 7 1994 through '07?
- 8 A. No, because there were very few labels
- 9 that mentioned rbST. And --
- 10 Q. How do you know that?
- 11 A. I've talked with the chief about that.
- 12 The chief informed me that the problem was
- 13 increasingly becoming one where enforcement action
- 14 was going to be taken because, for example, Dean,
- 15 or Smith Dairy used a content claim saying no
- 16 rbST, which is in direct violation of FDA
- guidance. So not on the basis of state rule, but
- on the basis that they were violating the FDA
- 19 guidance we were going to have to be taking some
- 20 action.
- 21 Q. When was the FDA guidance put in place?
- 22 A. I believe 1994.
- 23 Q. So the chief informed you that until
- 24 recently, there were no labels that contained the

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- 1 complaints regarding rbST labeling prior to the
- 2 time you took office?
- 3 A. I am not personally aware of any such
- 4 complaints.
- 5 Q. When is the first consumer complaint
- 6 that you are -- became aware of that was given to
- 7 the ODA regarding rbST labeling?
- 8 A. There were some complaints in October
- 9 of 2007 at the public meetings.
- 10 Q. So before the public meetings --
- 11 A. No.
- 12 **Q.** -- that --
- 13 A. They came out during the public
- 14 meeting.
- 15 Q. I understand. I was going off of that.
- 16 A. Excuse me.
- 17 Q. No, no problem. Prior to the public
- 18 meetings that you instituted regarding rbST
- 19 labeling that we're about to talk about, you're
- 20 not aware of any consumer complaints about rbST
- 21 labeling?
- 22 A. I am personally not aware of any before
- 23 October of 2007.
- 24 Q. And you didn't become aware from any

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- 1 existence, as we already talked about --
- 2 A. Right.
- 3 Q. -- since 1994.
- 4 A. Right.
- 5 Q. It was your understanding that prior to
- 6 the rule that you have now instituted in Ohio, the
- 7 FDA guidance was the law in the State of Ohio for
- 8 purposes of regulating rbST labeling; isn't that
- 9 right?
- 10 MR. PATTERSON: Objection; calls for a
- legal conclusion. You can answer.
- 12 A. I wasn't really concerned with the
- issue, so I wasn't really thinking about the
- 14 application of the FDA guidance before October of
- 15 2007.
- 16 **Q.** Well--
- 17 A. There wasn't a problem, because there
- were very few labels that had any mention of rbST.
- 19 I did know that the chief was concerned
- 20 about the Smith Dairy label being in violation of
- 21 the FDA guidance, and he was going to have to take
- 22 action.
- 23 Q. Isn't it correct, sir, that prior to
- 24 the establishment of the rule, the Ohio rule

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- 1 that's at issue in this lawsuit, ODA had the power
- 2 to regulate the Smith Dairy labeling rule under
- 3 the FDA guidance?
- 4 MR. PATTERSON: Objection; calls for a
- 5 legal conclusion. You can answer.
- 6 A. Yes. Under the FDA guidance, I was
- 7 aware that we had the ability to enforce the
- 8 guidance.
- 9 Q. So you didn't need the rule to enforce
- 10 the guidance against Smith Dairy and regulate that
- 11 label, correct?
- 12 A. Not in that limited case, no.
- 13 Q. Did you attend the first listening
- 14 session?
- 15 A. Yes.
- 16 Q. How many people attended?
- 17 A. I believe 75. It lasted about three
- 18 hours.
- 19 Q. Did you invite consumer
- 20 organizations --
- 21 A. I believe --
- 22 Q. -- to the listening session?
- 23 A. We gave public notice. We made a
- 24 very -- made a very public announcement that we

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- 1 safety, and welfare of the citizens of the State
- 2 of Ohio. I fell back on the FDA guidance giving
- 3 me direction in that particular area. It was very
- 4 clear to me that in order to have adequate
- 5 information, consumers should be afforded the full
- 6 intent of the FDA guidance.
- 7 Q. Sir, isn't it correct that the rule
- 8 that was ultimately promulgated by your department
- 9 is in conformance with the FDA guidance?
- 10 A. You're talking about the final rule --
- 11 Q. Yes.
- 12 A. -- that was approved?
- 13 Q. Yes.
- 14 A. It was in conformity, to my knowledge,
- 15 with the FDA guidance.
- 16 Q. Isn't it stronger than the FDA
- 17 guidance?
- 18 A. It is my belief that it is stronger
- 19 than the FDA guidance. As the guidance says,
- 20 "States should evaluate any labeling statement
- about rbST in the context of the complete label
- 22 and do what they think is necessary."
- 23 Q. What happened as a result of the
- 24 listening session?

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- 1 Q. Can I see what you're reading from?
- 2 A. Sure. I can give you copies of this.
- 3 It's underlined there.
- 4 Q. Right. Is this the FDA --
- 5 A. That's the FDA guidance.
- 6 Q. Right.
- 7 A. But let me also go beyond, if I may,
- 8 and that is my--
- 9 Q. There's no question pending.
- 10 A. Okay. Thank you.
- 11 Q. You had your chance in the affidavit.
- 12 A. Okay. Thank you.
- 13 Q. What's the purpose of the rule?
- 14 A. The purpose of the rule is to make sure
- that the consumers of Ohio have the most accurate,
- 16 complete, and balanced information concerning
- 17 dairy products.
- 18 Q. Is the purpose of the rule a need to
- 19 maximize consumer information and consumer choice
- 20 in dairy purchases?
- 21 A. The -- I think I explained what the
- 22 purpose of the rule is.
- 23 Q. Well, the way I characterized it, is
- 24 that the purpose of the rule, also?

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- 1 processors in the State of Ohio, or we will
- 2 stop -- we will go to court and get a cease order.
- 3 MR. PATTERSON: Off the record for a
- 4 minute.
- 5 MR. SUNSHINE: Sure.
- 6 (A discussion was held off the record.)
- 7 MR. SUNSHINE: Back on the record.
- 8 Q. Were you aware that Mr. Jones did an
- 9 investigation about the cost of relabeling?
- 10 A. Yes, I'm aware.
- 11 Q. Did you instruct him to do that?
- 12 A. Yes, I did.
- 13 Q. Did you participate in those
- 14 discussions?
- 15 A. I did not participate in the obtaining
- 16 of the information. Once the information was
- obtained, he shared the information. We talked
- 18 about it in great deal.
- 19 Q. What did he tell you?
- 20 A. He told me what the costs of -- that he
- 21 received from the industry, what the cost of
- 22 changing the labels would be.
- 23 Q. Did you instruct him to send letters
- 24 confirming those costs?

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- 1 Q. Isn't it correct, sir, that for a
- 2 national processor, if they had to change the
- 3 labels to conform with the State of Ohio, that it
- 4 was quite -- it is quite possible that they would
- 5 change the labels nationwide?
- 6 A. I have no idea of that industry. All's
- 7 I know is they change labels all the time. They
- 8 change it for 1 percent milk, 2 percent milk,
- 9 chocolate milk, for different advertising
- 10 purposes, different promotions. Labels are
- changed all the time, and I have no idea what the
- 12 cost is on a national scale.
- 13 Q. Did you ever talk to a national
- processor and ask them how they would go about
- changing labels to conform with the State of Ohio?
- 16 A. Yes. Yes.
- 17 Q. Who did you talk to?
- 18 A. Kraft Foods.
- 19 Q. What did they say?
- 20 A. They said it's very expensive to have a
- 21 set of labels only for Ohio and a different set
- 22 for the rest of the country.
- We pointed out to them that the label
- in Ohio, if they could be used throughout the

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- 1 country, they didn't have to change it. But if
- 2 they chose to, that was their choice.
- 3 Q. Did you read the declarations that I
- 4 submitted in connection with this case?
- 5 A. I did not read those.
- 6 Q. Did you know that those declarations
- 7 said that -- estimated that costs would range
- 8 between 130,000 and 240,000, not including
- 9 artwork, labor, dual storage costs? Did you know
- 10 that?
- 11 A. I've heard all sorts of figures from
- 12 the industry of different magnitude. Again, we
- believe that changing labels for the Ohio
- 14 market --
- 15 Q. Did -- I'm just asking you were you
- aware that the declarations that I submitted from
- 17 Organic Valley, White Wave, Horizon, and Aurora
- set forth estimates of between 130 and \$240,000?
- 19 A. To answer your question specifically --
- 20 Q. Excluding other costs, yes.
- 21 A. To answer your question specifically, I
- 22 was not aware.
- 23 Q. Can you comment today on the
- 24 discrepancy between those estimates and the

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- 1 estimate that you put forth in a declaration
- 2 submitted to the Court that a national processor
- 3 would only -- it would only cost them between
- 4 three and \$400?
- 5 A. We're talking about the labels for the
- 6 State of Ohio, redoing the labels for the State of
- 7 Ohio. We're not talking -- and our numbers; not
- 8 about what it might cost for that label to be
- 9 changed or to have a different set for Texas or
- 10 California or whatever.
- The most important point is our
- 12 obligation in the Department of Agriculture is to
- make sure the consumer has the most accurate
- information available, despite what cost it might
- be to the producer or processor, as long as it's
- 16 not too -- too difficult for them. And I believe
- the trade off we have in the rule is absolutely
- 18 correct.
- 19 Q. So, essentially, the cost is not really
- 20 your concern.
- 21 A. I didn't say that. I said it's a trade
- off, and I believe that the cost incurred by the
- processor is outweighed by the benefit to the
- 24 consumer.

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- 1 Q. And isn't one of the ways to get --
- 2 isn't one of the requirements for certification
- 3 that they not use rbST?
- 4 A. I do not know that.
- 5 Q. You did not know that?
- 6 A. Well, I would expect it to be so, but I
- 7 don't know that to be factual.
- 8 Q. Fair enough. Isn't it true that for
- 9 organic dairy farmers, the nonuse of rbST is
- 10 demonstrably true and verifiable?
- 11 MR. PATTERSON: I'm sorry. Can you
- 12 repeat that question?
- 13 (The record was read as requested.)
- 14 A. Yes.
- 15 Q. Did you know that the Organic Foods
- 16 Production Act provides penalties for misuse of
- 17 organic labels?
- 18 A. I would expect that to be true.
- 19 Q. Isn't it true that the Organic Foods
- 20 Production Act addresses false and misleading
- 21 statements in dairy labels?
- 22 A. I would expect that to be true.
- 23 Q. And isn't it correct that the Organic
- 24 Foods Production Act addresses directly false and

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- 1 Q. No personal knowledge of that?
- 2 A. I knew they sold milk in Ohio. I did
- 3 not know they sold milk in Pennsylvania.
- 4 Q. Now, isn't it correct that a label that
- 5 would be accepted in Pennsylvania using the
- 6 Pennsylvania guidance would not necessarily be
- 7 permitted under the Ohio rule?
- 8 A. As far as I know, that is correct.
- 9 Q. So isn't it correct that in the
- 10 instance of Reiter Dairy, as an example of many,
- that they would have to produce two separate
- 12 labels?
- 13 A. They could use the Ohio label in
- 14 Pennsylvania, and as far as I know, they could use
- 15 the Ohio label in any other state in the nation.
- 16 Q. So the purpose of the Ohio rule,
- really, is to create a national -- a new national
- 18 rule?
- 19 A. No.
- 20 MR. PATTERSON: Objection; asked and
- 21 answered. He's already answered the question
- about three times as to what the purpose of the
- 23 rule is.
- 24 A. No.

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- 1 Q. Section D of the rule says -- do you
- 2 have the rule in front of you? I assume, by the
- 3 way, the papers that you're referring to today is
- 4 just your file --
- 5 A. Yeah.
- 6 Q. -- of the papers relating to this
- 7 matter?
- 8 A. You can --
- 9 Q. That's fine. If you look at D, it
- says, "Statements may be considered to be false or
- 11 misleading." Do you see that?
- 12 A. Uh-huh.
- 13 Q. Why did you use the word "may"?
- 14 A. First of all, if we said the statement
- 15 "shall," we would be accused of being over
- 16 regulatory. We wanted to be able to indicate to
- the industry exactly what would be permitted, what
- we -- kind of give them a template. But if they
- 19 could come up with language that was just as much
- 20 in conformance with the interim guidance of the
- 21 FDA, we would accept it, even though it wasn't
- 22 exactly as we enumerated.
- 23 Q. Who would decide whether a particular
- 24 statement would be considered false or misleading?

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- 1 A. Ultimately, that might be my decision
- 2 upon the advice of counsel and our dairy chief.
- 3 Q. So "may" gave you discretion rather
- 4 than "shall"?
- 5 A. "May" gave the industry an opportunity
- 6 to present alternative language that might be
- 7 easier for them or more important for them to use
- 8 as long as it met the FDA guidance.
- 9 Q. Are there circumstances that you can
- 10 think of when a statement may not be false
- 11 or -- and misleading, even if it indicates the
- 12 absence of a compound not permitted by the United
- 13 States, by the federal government?
- 14 A. Excuse me. Would you repeat the
- 15 question?
- 16 Q. Sure.
- 17 (The record was read as requested.)
- 18 MR. PATTERSON: Is your question the
- 19 absence of a compound in a product or a
- 20 composition?
- 21 MR. SUNSHINE: Either.
- MR. PATTERSON: I object, then, to your
- 23 question if you mean either, because it's --
- 24 MR. SUNSHINE: Let me ask my question.

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- 1 claim on the use of rbST, whether it be organic or
- 2 nonorganic, because it is not verifiable.
- 3 Q. In other words, your understanding of
- 4 the problem with rbST free is that it's not
- 5 verifiable? You can't verify whether there is or
- 6 isn't rbST in the milk?
- 7 A. That is correct.
- 8 Q. Isn't it correct that rbST cannot
- 9 conceivably get into milk if it is not used in
- 10 production?
- 11 A. If it is not used in production. If it
- is not given to herds, then they should use a
- 13 production claim.
- 14 Q. Isn't it correct that rbST can't get in
- milk in any way other than using it in production?
- 16 Using the chemical made by Monsanto in production,
- isn't that the only way that rbST can get in milk?
- 18 Is that your understanding?
- 19 A. My understanding, again, is that the
- 20 FDA guidance, as indicated --
- 21 Q. I'm not asking you that.
- 22 A. I understand what you're saying. I'm
- 23 answering what I believe is true.
- 24 Q. Okay. Do you believe that rbST can get

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- 1 in milk in any way other than by using rbST
- 2 product made by Monsanto in production?
- 3 A. I do not believe that can get in any
- 4 other way.
- 5 Q. Now, your belief that rbST free is
- 6 false and misleading is based on the fact that you
- 7 can't detect whether it's true; is that correct?
- 8 A. That is correct.
- 9 Q. What if you can detect it? Would it
- 10 change? Would it change your opinion of whether
- 11 this rule is valid or not?
- 12 A. That's a hypothetical question that I
- 13 have no idea what the facts might be in that
- 14 particular case.
- 15 Q. Okay. So based on your understanding
- 16 that you can't detect whether rbST is in milk, you
- 17 believe this rule is valid?
- 18 A. I believe it falls --
- 19 MR. PATTERSON: Can I clarify the
- 20 question? Are you saying the rule as it regards
- 21 compositional claims?
- MR. SUNSHINE: I don't care what you
- 23 call it. I'm talking about the two words, rbST
- 24 free. Whatever you call them, compositional,

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- 1 Q. Contiguous?
- 2 A. Yeah. Contiguous. I'm sorry.
- 3 Q. I was trying to be flip --
- 4 A. Okay.
- 5 Q. -- but my question was somehow the rule
- 6 doesn't allow asterisks and to put the disclaimer
- 7 lower on the label, right?
- 8 A. That is correct.
- 9 Q. Okay. Why?
- 10 A. So that consumers have all relevant and
- 11 complete information available to them in
- 12 juxtaposition, where they can see both claim and
- 13 disclaimer.
- 14 Q. Are you aware that the acting director
- of the United States Department of Health & Human
- 16 Services wrote that the use of asterisks to link a
- 17 footnote is commonplace and communicates
- 18 effectively to consumers and that consumers had
- 19 few problems with this format device?
- 20 A. I was not aware of it. And from my own
- 21 personal experience watching people in
- 22 supermarkets, especially senior citizens, trying
- 23 to read labels, I feel that is absolutely
- 24 incorrect.

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Q. So you disagree with the director --1 2 A. Yes. 3 -- on that point? Q. A. On that point, yes. 4 5 MR. SUNSHINE: All right. I think this 6 is a good place to turn it over to IDFA. 7 8 CROSS-EXAMINATION 9 BY MS. YOVIENE: 10 Q. Thank you. Good morning, 11 Director Boggs. Thank you for coming. 12 Following on the asterisks question, 13 besides your own opinion about the asterisk, did the department perform any formal surveys or 14 studies to determine whether the asterisk would be 15 helpful, provide information to consumers in a way 16 that the Department of Health & Human Services 17 said it would? 18 19 We didn't do surveys, but I was shown Α. 20 any number of labels, quite a few different labels 21 as to how creative processors could be in making 22 sure that that information was not readily 23 available to consumers by the use of very small 24 print, by washing the color out to such a degree

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- 1 evidence of that?
- 2 A. I have anecdotal experience. You said
- 3 no consumer. I've talked to many consumers in
- 4 stores and asked them about this, and they have
- 5 agreed that oftentimes it's hard to understand
- 6 labels, especially when the print is so small.
- We didn't do a survey. This isn't
- 8 based on some sort of widespread survey, but I
- 9 have talked to consumers that have expressed that
- 10 problem.
- 11 Q. And does the department engage -- you
- 12 have labeling authority over other food products,
- 13 **right?**
- 14 A. Uh-huh.
- 15 Q. Is the department prohibiting the use
- of asterisks on other food products?
- 17 A. I do not believe so. But we, as we
- 18 review these labels in the future, may not.
- 19 Q. Now, the consumers that you claim to
- 20 have talked to in a supermarket, can you tell us
- 21 who those consumers were, what their backgrounds
- 22 were?
- 23 A. I just go shopping, and oftentimes,
- 24 when I stop by the dairy case, I ask questions of

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- 1 consumers.
- 2 Q. Right.
- 3 A. I don't know their names or their
- 4 backgrounds. As I have indicated, this is not a
- 5 sample of public opinion. It's not an extensive
- 6 survey. But I was very curious about what people
- 7 felt about labels.
- 8 Q. But you weren't aware of the asterisk
- 9 being a problem before you started the listening
- 10 session?
- 11 A. I've been aware of that for a long
- time, and I felt it was fairly duplicitous of the
- industry to take FDA guidance and try to hide it.
- 14 Q. When you say "long time," earlier you
- said you weren't aware of any controversy of the
- 16 rbST label before October, 2007, correct?
- 17 A. For a long time I was aware of the
- disclaimer, not that there was a controversy over
- 19 rbST.
- 20 Q. You were -- what do you mean --
- 21 A. There's been rbST milk in Ohio
- 22 for -- excuse me. There have been labels dealing
- 23 with the presence or nonpresence of rbST milk in
- 24 Ohio for some time. There just hasn't been a

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Robert J. Boggs

September 3, 2008

- 1 Q. Okay. Now, earlier you said the Ohio
- 2 rule could be used in all 50 states.
- 3 A. To the best of my understanding. I'm
- 4 also aware that Utah might not allow any reference
- 5 to rbST. So that, obviously, depends on what
- 6 other states are going to do with their rules and
- 7 law in the future.
- 8 Q. Okay. So you can't be 100 percent
- 9 sure --
- 10 A. No.
- 11 Q. -- that the Ohio rule --
- 12 A. No.
- 13 Q. Let me finish my question.
- 14 A. Sure.
- 15 Q. You aren't 100 percent sure that the
- Ohio rule can be used in all 50 states?
- 17 A. I cannot be sure.
- 18 Q. Okay. Are you familiar with national
- 19 retailers' warehousing methodologies for
- 20 distribution?
- 21 A. No.
- 22 Q. Okay. So if I told you that dealers
- 23 doing business with national retailers such as
- 24 Shamrock Foods deliver product to the retailer's

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```
State of Ohio : CERTIFICATE
 1
     County of Franklin: SS
 2
 3
         I, Reva Chafin Mundy, a Notary Public in and
 4
     for the State of Ohio, certify that Robert J. Boggs
 5
     was by me duly sworn to testify to the whole truth
     in the cause aforesaid; testimony then given was
 7
     reduced to stenotype in the presence of said
 8
     witness, afterwards transcribed by me; the
 9
     foregoing is a true record of the testimony so
10
     given; and this deposition was taken at the time
11
     and place specified on the title page.
12
         Pursuant to Rule 30(e) of the Fed. R. Civ. P.,
13
     the witness and/or the parties have not waived
14
     review of the deposition transcript.
1.5
         I certify I am not a relative, employee,
16
     attorney or counsel of any of the parties hereto,
17
     and further I am not a relative or employee of any
18
     attorney or counsel employed by the parties hereto,
19
     or financially interested in the action.
20
         IN WITNESS WHEREOF, I have hereunto set my hand
21
     and affixed my seal of office at Columbus, Ohio, on
22
     September 5, 2008.
23
     Reva Chafin Mundy, Notary Public - State of Ohio
24
     My commission expires May 23, 2012.
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Realtime - Videoconferencing - Trial Presentation - Video Spectrum Reporting LLC

135 September 3, 2008

Robert J. Boggs

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Spectrum Reporting LLC

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

International Dairy : Foods Association and Organic Trade : Association,

:

Plaintiffs, Case No. 2:08-CV-628

2:08-CV-629

vs. Judge Graham

:

Robert J. Boggs,
Director, Ohio
Department of
Agriculture,:

Defendants. :

- - - - -

DEPOSITION OF LEWIS R. JONES

- - - - -

Taken at Schottenstein, Zox & Dunn Co., LPA 250 West Street, 7th Floor Columbus, OH 43215 September 3, 2008, 11:53 a.m.

- - - - -

Spectrum Reporting LLC 333 Stewart Avenue, Columbus, Ohio 43206 614-444-1000 or 800-635-9071 www.spectrumreporting.com

Lewis R. Jones September 3, 2008

- 1 Q. But if you change an answer, I can
- 2 comment on the fact that you changed an answer and
- 3 comment adversely on that fact. Do you understand
- 4 what I just said?
- 5 A. Yes.
- 6 Q. For that reason, among others, it's
- 7 important that you give your most truthful and
- 8 complete testimony today. If you don't understand
- 9 any questions or any words that I use, please tell
- 10 me. If you answer any question, I and anyone
- 11 reading this transcript later will believe that
- 12 you understood the question. Do you understand
- 13 what I just said?
- 14 A. I understand.
- 15 Q. Okay. Do you have any questions about
- 16 the process?
- 17 A. No.
- 18 Q. Okay. Why was the issue of rbST an
- 19 emergency?
- 20 A. It was an emergency because we had a
- 21 lot of contacts from processors, producers, and
- 22 consumers, because they were confused as to
- 23 labeling issues mainly brought about by the policy
- 24 change that the State of Pennsylvania Department

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Lewis R. Jones September 3, 2008

- 1 of Agriculture issued in October 22nd of last
- 2 year. They were concerned what is Ohio going to
- 3 do.
- 4 Q. Who did you get contacts from?
- 5 A. Got contacts from most of the
- 6 processors in Ohio, but mainly the grade A
- 7 processors, milk bottlers, had contacts from
- 8 producers, and several contacts by e-mail and
- 9 phone calls from consumers throughout the nation.
- 10 **Q.** And when did those -- when did those
- 11 contacts come in?
- 12 A. They started immediately after October
- 22nd, the end of October through the time that we
- 14 issued the final rule.
- MR. PATTERSON: Can we go off the
- 16 record for a minute.
- 17 (A short recess was taken.)
- MR. SUNSHINE: Back on the record.
- 19 Q. Am I correct from your last answer that
- you received no consumer complaints about rbST
- 21 labeling prior to October, '07 in your capacity as
- 22 chief of the dairy division?
- 23 A. We received some, but very little. The
- 24 barrage started after October 22nd, but we had had

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Lewis R. Jones September 3, 2008

- 1 some concerns before that.
- 2 Q. Well, who did you receive concerns
- 3 from?
- 4 A. Don't have a complete record, but
- 5 somewhere -- mostly from consumers.
- 6 Q. How many prior to October 22nd of '07
- 7 did you receive, that is, complaints from
- 8 consumers about misleading labels relating to
- 9 **rbST?**
- 10 A. They weren't all complaints. Most of
- 11 them were complaints. Some were concerns about I
- want to know what's in my dairy product. I want
- 13 to know what's in my milk.
- 14 Q. Were those e-mails, letters, what?
- 15 A. Mostly e-mails, I believe.
- 16 Q. Where are those e-mails?
- 17 A. I think they were sent to make copies.
- I have them on my computer, and I think we made
- 19 copies and provided them to you.
- 20 Q. And are you sure that you have e-mails
- 21 prior to October 22nd of '07 that commented
- 22 adversely about rbST labeling on milk products?
- 23 A. I can't say that I'm sure of that. I
- 24 didn't make a date as to when they started, but we

Spectrum Reporting LLC

10 September 3, 2008

Lewis R. Jones

- 1 had very few -- very few, if any, really --
- 2 Q. Okay.
- 3 A. -- before.
- 4 Q. It's possible you had none before
- 5 October 22nd of '07; is that correct?
- 6 A. Possibly we had not. That's possible,
- 7 yes.
- 8 Q. And if you had any --
- 9 A. We would have --
- 10 Q. You would have produced them to me,
- 11 right?
- 12 A. We would have produced them, yes.
- MR. PATTERSON: Off the record.
- 14 (A discussion was held off the record.)
- MR. SUNSHINE: Back on the record.
- 16 Q. Would you agree that Monsanto played a
- key behind-the-scenes role in the process of
- 18 preparing this rule?
- 19 A. I'd agree that they played a role. I
- 20 don't know if it was a key role. I'm not sure to
- 21 the extent of what they played.
- 22 Q. Well, you were the main contact with
- 23 Monsanto during this process, weren't you, on
- behalf of the ODA?

Lewis R. Jones

- 1 A. Yes.
- 2 Q. So you know what role they played,
- 3 right?
- 4 A. Yes.
- 5 Q. In fact, you're the person who
- 6 interacted with them, correct?
- 7 A. I had conversation with Monsanto, and
- 8 mostly in a group setting or a group e-mail
- 9 setting.
- 10 Q. Well, you had numerous e-mails to and
- 11 from Monsanto, didn't you?
- 12 A. To and from Monsanto I had some. I
- don't know if I'd classify it numerous that was
- 14 just to Monsanto, but I had some that was to
- Monsanto and some to a mail group that included
- 16 Monsanto.
- 17 Q. Well, they weren't all -- not all the
- e-mails were to or from or to or from the mail
- 19 group, were they?
- 20 A. Not all of them, no.
- 21 Q. Isn't it correct --
- 22 A. Most of them -- most of them I was
- 23 responding to questions that they asked.
- 24 Q. Isn't it true that you had a number of

Lewis R. Jones

- 1 one-on-one e-mails with Mark Armfelt?
- 2 A. I don't know what that number is, but I
- 3 had some e-mails with Mark Armfelt, yes.
- 4 Q. And you understood him to be a Monsanto
- 5 employee, right?
- 6 A. I understand that. But some of those,
- 7 some of those e-mails, were prior to the October
- 8 setting. Some of them had to do with him working
- 9 with us to get a speaker at a conference in 2007,
- 10 I believe it was. But all the e-mails with
- 11 Monsanto or Mark Armfelt were not regarding the
- 12 labeling. There were other matters.
- 13 Q. Well, isn't it correct that in the
- period of October, '07 through April, '08, you
- communicated by e-mail on a number of occasions
- 16 with Mark Armfelt concerning the issues
- 17 relating -- the issues that ultimately resulted
- with the rule that's at issue in this lawsuit?
- 19 A. On occasion, but I don't know what that
- 20 number is.
- 21 **Q**. Okay.
- 22 A. The majority of my contact with him was
- 23 him being part of a mail group.
- 24 Q. Now, apart from those e-mails, did you

Lewis R. Jones

- 1 Q. Have you ever read the federal
- 2 guidance?
- 3 A. Yes, I have.
- 4 Q. Did you read it before October of '07?
- 5 A. Yes, I did.
- 6 Q. You were using the federal guidance
- 7 prior to October of '07 to regulate dairy labeling
- 8 in the State of Ohio, correct?
- 9 A. We were using it loosely, I would say.
- 10 Q. You weren't using any other statutes,
- 11 correct?
- 12 A. No.
- 13 Q. Why do you say "loosely"?
- 14 A. Well, because we weren't -- we weren't
- 15 enforcing it.
- 16 Q. Weren't enforcing it because there were
- 17 no complaints, right?
- 18 A. That's correct.
- 19 Q. Kind of if it ain't broke, don't fix
- 20 it?
- 21 A. Yes. But then when you get thousands
- of e-mails about a subject, it's time to take some
- 23 kind of action.
- 24 Q. We'll get to that in a minute. I'm

Lewis R. Jones

- 1 just trying n to set the stage for that.
- 2 Prior to October of '07, the federal
- 3 guidance was working fine, correct?
- 4 A. Yes.
- 5 Q. Let's talk about the thousands of
- 6 e-mails. What are they?
- 7 A. Pardon?
- 8 Q. How can you describe them, the
- 9 thousands of e-mails you just referred to?
- 10 A. Well, as I stated earlier, they came
- 11 from all over the country. Most of them didn't
- 12 come from Ohio. But we received e-mails from
- 13 several states in the union, as far away as from
- 14 California, Texas.
- 15 Q. Complaining about misleading labels?
- 16 A. No, complaining about they want to see,
- you know, no hormones or no rbST in milk, because
- 18 they don't want artificial hormones in their
- 19 product.
- 20 Q. So people were writing to you saying
- 21 that they didn't -- they wanted to be told whether
- 22 or not there were hormones or rbST in their
- 23 product, right?
- 24 A. That's correct.

- 1 and letters were opposed and about 70 were in
- 2 favor. Did you read that at the time?
- 3 A. I recall reading it, yes. I've read so
- 4 many documents on this case --
- 5 Q. Okay. I understand, sir.
- 6 A. -- I don't remember every sentence.
- 7 Q. Well, when you read that, did you
- 8 dispute it?
- 9 A. No. No.
- 10 Q. You didn't go back and check, because
- 11 you didn't need to?
- 12 A. No. No. I didn't go back and check.
- MR. SUNSHINE: All right. Off the
- 14 record.
- 15 (A short recess was taken.)
- MR. SUNSHINE: Let's go back on the
- 17 record.
- 18 Q. I believe you just testified that most
- of the complaints that you did receive in October
- 20 of -- in or about October of '07 were complaints
- 21 in the nature of consumers wanting to know whether
- 22 the milk contained hormones or rbST. Do I have
- 23 that right?
- And what were those numbers that you

- 1 had, 2700 to 70 or something?
- 2 Q. Well, no. I just wanted to know -- you
- 3 said that -- let's back up. I believe you
- 4 testified that the reason why it became an
- 5 emergency was because you got a flurry of consumer
- 6 inquiry.
- 7 A. Inquiries, yes.
- 8 Q. Both written and oral, right?
- 9 A. Yes.
- 10 Q. And the nature of the inquiry was that
- consumers wanted to know whether the milk that
- 12 they were buying contained hormones or contained
- 13 **rbST**.
- 14 A. Yes. Consumers were confused, so we
- wanted to clear up the confusion. And we had 2700
- against our rule, but if we eliminate the
- duplicates, in other words, the mass e-mails, we
- would probably have been down around the 70
- 19 number, the same as the for, because many of these
- e-mails, I would receive, you know, 10, 20, 30
- e-mails a day, and they would all be identical,
- 22 the same wording. In other words, they were mass
- produced, and they were coming from all over the
- 24 country.

Lewis R. Jones

- 1 Q. So you discounted those?
- 2 A. Pardon?
- 3 Q. So you discounted those?
- 4 A. No, I didn't discount them. They're
- 5 included in that 2700.
- 6 Q. Consumers were confused, but they
- 7 weren't misled, were they?
- 8 A. I think some of them were.
- 9 Q. How could you tell which ones were
- 10 misled and which ones were simply confused?
- 11 A. Well, the ones that said I don't want
- that product in my milk or I don't want that in my
- dairy products, I think they were misled, because
- 14 there was no way to measure whether it was in the
- 15 milk or not.
- 16 Q. Well, there's a way to measure that
- there's no rbST for organic products, isn't there?
- 18 A. I don't know of any way.
- 19 Q. Isn't it correct that in order to be
- 20 certified organic, you must be able to show to the
- 21 federal government that there is no rbST added
- 22 to -- in any part of the production?
- 23 A. When I look at the organic
- 24 certification, they talk mostly of drugs,

Lewis R. Jones

- 1 Q. Isn't rbST an artificial hormone?
- 2 A. Yes.
- 3 Q. So is it your understanding that
- 4 excluded methods as defined in the National
- 5 Organic Program includes rbST?
- 6 A. Yes. But I think your question was can
- 7 it be measured or tested for.
- 8 Q. Isn't it correct that in order to be
- 9 certified as organic, the certification program
- 10 includes a showing that there is no rbST in the
- 11 product?
- 12 A. I believe that's correct. But I don't
- 13 know what that "showing," the term "showing"
- 14 means.
- 15 Q. Isn't it correct that certified organic
- 16 farmers are required to verify that they do not
- 17 use rbST?
- 18 A. That has been added, yes, to their
- 19 qualifications, yes.
- 20 Q. All right. So just for organics, if
- 21 that's true, why is it misleading to say rbST
- 22 **free?**
- 23 A. Because reading a label that says rbST
- free is a composition claim. RbST free is

Lewis R. Jones

- 1 Q. They're not allowed to give their cows
- 2 rbST.
- 3 A. Yes.
- 4 Q. What is wrong with putting on their
- 5 labels -- just talking about my client, the
- 6 organic industry, what is wrong with putting on
- 7 their labels words to the effect of we don't give
- 8 the cows rbST, or something to that effect?
- 9 What's wrong with that? Why is that misleading
- and why is that confusing?
- 11 A. It's confusing because most people
- would think rbST is a food hazard or a food safety
- issue. And if that product says we do not treat
- our cows with rbST, period, without a disclaimer,
- that means that it can be assumed that
- 16 conventional milk does have, or milk from cows
- treated with rbST, which could be -- some people
- 18 might think is a minus factor in their milk,
- 19 something that people don't want.
- 20 Q. You were getting no e-mails from any
- 21 consumers that said what you just said, were you?
- 22 A. I got e-mails that said various things.
- 23 Q. Let me ask you very directly: Did you
- 24 get any e-mails where a consumer said I'm confused

- 1 and misled because labels say no rbST added, but
- 2 they don't have the -- but they don't have the
- 3 disclaimer, or words to that effect? Did anyone
- 4 ever say that?
- 5 A. I can't answer the question. I don't,
- 6 you know --
- 7 Q. None come to mind, do they?
- 8 A. Not at this time, no.
- 9 Q. All right. And if such e-mails or
- 10 letters exist, you would have produced them to
- 11 us --
- 12 A. Yes. Yes.
- 13 **Q.** -- in our document production?
- 14 A. Yes.
- 15 Q. It would be in that group that we're
- 16 talking about?
- 17 A. Yes, it would.
- 18 Q. Okay. You know that the Pennsylvania
- rule excludes the organic industry, don't you?
- 20 A. I know that they're saying that the
- 21 organic -- it doesn't require the disclaimer.
- 22 Q. For the reason that we just went over,
- 23 shouldn't Ohio have the same exception?
- 24 A. I don't know what Pennsylvania's

Lewis R. Jones

- 1 Q. And you ran it?
- 2 A. It was my suggestion to him that we
- 3 should have such a session, and I was the emcee,
- 4 whatever. It was just a --
- 5 Q. How did you decide who to invite?
- 6 A. Well, we tried to -- we tried to hit
- 7 most of the -- the interested parties. We invited
- 8 consumers. We invited production -- producing
- 9 groups, processor groups.
- 10 It happened so quickly, you know. We
- 11 decided after -- it was around the 25th of
- 12 October -- to have this session on November the
- 13 6th. So, you know, that covered a weekend, also.
- 14 So we had five to six working days to put this
- 15 session together. And we wanted to do it quickly,
- 16 because we were getting a lot of concerns,
- 17 contacts, and e-mails, phone calls.
- 18 Q. Did you ever perform a survey of
- consumers to determine whether they were misled by
- 20 any dairy labels?
- 21 A. Not an official survey, no.
- 22 Q. Did you ever conduct an analysis of
- 23 that question?
- 24 A. No.

- 1 Q. But I thought the reason for the rule
- 2 was because consumers were being misled. Why
- 3 didn't you conduct an analysis of whether they
- 4 were misled?
- 5 A. We did not have time. 2700 e-mails
- 6 were enough to tell us that they were misled.
- 7 Q. That they were misled?
- 8 A. Misled, or didn't understand the
- 9 meaning of the labels.
- 10 Q. The 2700 e-mails I thought we
- identified were in opposition to your rule.
- 12 A. They were. But the e-mails --
- 13 Q. Why didn't -- go ahead.
- 14 A. The e-mails stated, you know -- just
- 15 from reading the e-mails, we understood that they
- 16 didn't understand the rule or understand the
- meaning of the labels.
- 18 Q. So it is your testimony that your
- belief that consumers were being misled by dairy
- 20 labels was based on the fact that 2700 consumers
- 21 wrote e-mails and letters in opposition to the
- 22 rule. Is that -- do I have that right?
- 23 A. They weren't all 27 in opposition to
- the rule. They were misunderstanding of the rule.

- 1 Some of them were wanting an explanation.
- 2 Q. Well, you didn't do a -- I'm sorry.
- Were you continuing? I didn't mean to interrupt.
- 4 A. Go right ahead.
- 5 Q. Okay. You didn't do a survey, right?
- 6 A. No.
- 7 Q. You didn't do an analysis, right?
- 8 A. That's correct.
- 9 Q. You just took from the e-mails that
- 10 consumers were being misled. Is that essentially
- 11 your testimony?
- 12 A. Let's not give the e-mails so much
- 13 credit for what we did. I would like to say that
- 14 our rule resulted from not only those letters and
- e-mails, but from -- not only our listening
- session on November the 6th, but also our advisory
- 17 council meetings on December 6th and December the
- 18 19th.
- 19 Q. I'm going to get to those, but go
- 20 ahead.
- 21 A. And also our two hearings. We didn't
- 22 discard those live sessions.
- 23 Q. But during the live sessions, during
- 24 the advisory committee meetings which we'll get to

Lewis R. Jones

- 1 in a little more detail in a minute, and the
- 2 hearings, there were no analyses performed on
- 3 whether or not consumers were actually misled by
- 4 dairy labels, was there?
- 5 A. There was no numerical analysis, no.
- 6 But we -- you've seen the comments from
- 7 those -- from those hearings and listening
- 8 sessions.
- 9 Q. So it was just your sense based on
- 10 those advisory committee meetings, listening
- sessions, and the hearings that consumers were
- 12 being misled?
- 13 A. It wasn't my sense. It was a general
- 14 conclusion from the meetings that we had
- discussing the hearings and listening sessions.
- 16 **Q.** Conclusion by whom?
- 17 A. By ODA staff.
- 18 Q. Unanimous?
- 19 A. Yes.
- 20 Q. Who made the decision?
- 21 MR. PATTERSON: Who made what decision?
- 22 A. What decision? Yeah.
- 23 **Q.** To implement the rule.
- 24 A. That would be the director. The

Lewis R. Jones

- 1 director, that was his decision.
- 2 Q. Did you participate in the decision?
- 3 A. I gave input, but the final decision
- 4 was Director Boggs.
- 5 Q. Did anyone ever say during the process
- 6 of implementing the decision that hey, we should
- 7 do a study or a survey of consumer satisfaction
- 8 with the labels as it now stands? Did anyone ever
- 9 say that?
- MR. PATTERSON: Same objection;
- instruct the witness not to answer to the extent
- 12 it calls for privileged attorney-client
- 13 communications.
- 14 Q. Can you answer the question?
- 15 A. I can't answer the question.
- MR. PATTERSON: I'm instructing him not
- 17 to answer. I think the question calls for
- 18 confidential attorney-client communications to be
- 19 disclosed.
- 20 Q. Did the subject of performing a survey
- 21 or an analysis like that come up during that
- 22 period?
- MR. PATTERSON: Same objection; to the
- 24 extent -- I don't think the witness can answer

Lewis R. Jones

- 1 without disclosing attorney-client communications,
- 2 so I'm not -- just to be clear for the record, I'm
- 3 not objecting to questions regarding what the
- 4 purpose of the rule was or what conduct -- what
- 5 activities were conducted by ODA with regard to
- 6 it, but with regard to all the questions about
- 7 what subject came up or was discussed with regard
- 8 to these issues, the witness testified ten minutes
- 9 ago or so that all the communications involved
- 10 legal counsel. And to that extent, questions that
- are directed to what was discussed or what came up
- in these discussions all relate to attorney-client
- 13 communications.
- 14 Q. Did you have discussions about
- performing a survey or an analysis like I just
- 16 described with anyone other than attorneys?
- 17 A. No.
- 18 Q. Isn't it correct that the ODA, as the
- director of the ODA, you never concluded that the
- 20 existing labeling that existed prior to the rule
- 21 was actually misleading?
- 22 A. Repeat your question.
- 23 Q. Did you ever conclude that the labeling
- that existed prior to the rule being enacted was

Lewis R. Jones

- 1 misleading, actually misleading?
- 2 A. We considered that it was misleading.
- 3 But since we weren't getting complaints and it
- 4 wasn't a food safety issue, we didn't pursue it.
- 5 Q. When did you first conclude it?
- 6 A. When did we conclude?
- 7 Q. You just testified that you concluded
- 8 it, but didn't pursue it prior to the rule.
- 9 A. Oh, we concluded it after we got
- 10 bombarded with consumer and producer and processor
- inquiries as to what Ohio was going to do now that
- 12 our neighboring state, Pennsylvania, had issued a
- 13 new policy.
- 14 Q. Who chose the members of the advisory
- 15 committee?
- 16 A. Director Boggs.
- 17 Q. Was there an effort made to put
- 18 consumers on the committee?
- 19 A. Yes.
- 20 Q. What was the effort?
- 21 A. Phone calls, e-mails.
- 22 Q. Did you get any?
- 23 A. Yes.
- 24 Q. Who?

Lewis R. Jones

- 1 Q. And consumers were choosing option No.
- 2 1 because they believed -- because they said they
- 3 believed they were being misled?
- 4 A. I didn't determine whether it was
- 5 consumers choosing No. 1 or processors or et
- 6 cetera. We -- we were all one body. We weren't
- 7 consumers on this side of the room and processors
- 8 on this side and --
- 9 Q. Did the advisory committee make a
- 10 recommendation?
- 11 A. Not an official recommendation, but
- 12 from the comments that we had on the last day,
- most of them wanted us to follow the interim
- 14 guidance, which if you look at our final rule,
- 15 it's almost identical to the interim guidance that
- was written back in 1994.
- 17 Q. If it was almost identical, then why
- 18 did you need it?
- 19 A. Oh, we had to make some clarifications.
- 20 For one thing, it -- because it said -- the
- 21 interim guidance said the states shall issue their
- 22 regulatory -- in other words, they left it up to
- 23 the states to define the regulatory action.
- 24 Q. But you adopted a rule that actually is

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- 1 more strict than the interim guidance, right?
- 2 A. Might be a little, but, you know, the
- 3 interim guidance, we were talking -- we spent a
- 4 lot of time or you asked me questions about
- 5 organic. The interim guidance makes no
- 6 distinction between conventional milk and organic
- 7 milk.
- 8 The FDA did say that the state should
- 9 establish their own regulatory requirements.
- 10 Q. The interim guidance, the FDA guidance
- does not even require contextual language, right?
- 12 A. No. It's not required, but they said
- 13 that both the presence and the absence of
- 14 information are relevant to whether labeling is
- 15 misleading.
- 16 Q. And the interim guidance says that a
- 17 statement like "From cows not treated with rbST"
- is not necessarily misleading, correct?
- 19 A. But they said --
- 20 **Q.** Is that correct?
- 21 A. That's correct.
- 22 Q. All right. Thank you.
- 23 A. In itself it's not misleading. But
- 24 they did say, you know, a disclaimer -- they

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- 1 talk about, you know, the cost of changing labels.
- 2 MR. PATTERSON: Are you talking about
- 3 his affidavit?
- 4 MS. YOVIENE: Yes.
- 5 MR. PATTERSON: That's right here.
- 6 Here it is. That has the attachments.
- 7 Q. Explain to me what changes those costs
- 8 reflect.
- 9 A. I did not ask what changes. My
- 10 question was what will it cost your company to
- 11 conform to the rules as they exist today, what
- would it cost your company per label. I did not
- ask what's included in that \$300 or that \$400.
- 14 Q. So you don't know if that was simply
- 15 just changing a plate?
- 16 A. What would it cost your company. I
- don't know what it included.
- 18 Q. Okay. Just answer the question. You
- don't know if that was just limited to what it
- would take to change a label plate for printing,
- 21 correct?
- 22 A. Correct.
- 23 Q. And you don't know if that included or
- excluded design work that would have to be done to

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- 1 change a label, correct?
- 2 A. I don't, but I assume that those are
- 3 costs included.
- 4 Q. But you don't know, because you didn't
- 5 ask the question.
- 6 A. I don't know.
- 7 Q. Okay. And you don't know whether that
- 8 excluded or included the cost of artwork?
- 9 A. I know that my question asked for what
- 10 it would cost your company.
- 11 Q. It's a yes or no question.
- 12 A. I didn't know what it --
- MR. PATTERSON: He's trying to answer
- 14 the question.
- 15 A. I'm answering --
- MR. PATTERSON: He answered it that he
- 17 understood this was the cost for the company to
- 18 comply with the rule. So he's already answered
- 19 the question a couple of times.
- 20 Q. Okay. Did you consider and ask
- 21 questions about internal review processes that
- would be required for national dealers doing
- 23 business with national retailers to make sure
- 24 consistency is accomplished? Did you inquire

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- 1 already supplied us with labels that do conform
- 2 with our rule.
- 3 Q. Now, speaking of that, do you have
- 4 any -- you don't know that they actually have made
- 5 changes to their labels. They've just submitted
- 6 you a template, right?
- 7 A. Yes. That's correct.
- 8 Q. So they haven't, to your knowledge,
- 9 gone through and asked their customers can you
- 10 live with this.
- MR. PATTERSON: Objection; calls for
- 12 speculation.
- 13 Q. I'm asking if he has knowledge.
- 14 A. I would have no way of knowing that.
- 15 Q. Okay. So you don't have any knowledge?
- 16 A. But, you know, all I can look at is
- this company, Dean Foods, Reiter, Springfield has
- 18 submitted labels we've approved. In other words,
- 19 they've said this is what we can do. Will you
- approve them? And we've given them the approval.
- 21 Yes, those labels do conform to our --
- 22 Q. Do you have a letter saying this is
- 23 what we can do, or do you have a letter just
- 24 asking to approve it?

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- 1 A. Just asking to approve it.
- 2 Q. Okay. Just wanted to be clear. So
- 3 just to be sure, if a plant is in Pennsylvania and
- 4 they have a retailer that says I'm not willing to
- 5 have my labeling changed. I'm complying -- the
- 6 plant's in Pennsylvania. The retailer's receiving
- 7 a label that complies with Pennsylvania's
- 8 guidance. And the retailer says I don't want you
- 9 to change my labels, but I still want to sell in
- 10 Ohio. That dealer won't be able to sell their
- 11 product in Ohio?
- 12 A. As the rule is written today, that's
- 13 correct.
- 14 Q. Did the department consider when it was
- considering -- looking at the issue of cost, did
- 16 you consider the issue of how much it would cost
- to comply with different state regulations, you
- 18 know, changing to -- if somebody already has a
- 19 label in place and it's in compliance with all
- 20 other state regulations and now they have to
- 21 change for Ohio, did you consider that?
- 22 A. We considered what it would cost to
- change the label.
- 24 Q. Just for Ohio, though.

Lewis R. Jones

- 1 A. Just for the Ohio label, yes.
- 2 Q. Okay. But did you consider the next
- 3 step, which is if they changed -- if they have a
- 4 national brand and they're shipping it to one
- 5 warehouse in the country to a retailer and they
- 6 want to keep shipping just one brand to one
- 7 warehouse in the country and they want to sell
- 8 into Ohio, they have to make a change, right? Did
- 9 you ask the next question, which is if I make this
- 10 change to comply with Ohio, how much is it going
- 11 to cost these plants to now go comply with the
- 12 other states?
- 13 A. No, because that would be thousands of
- 14 different answers. It would be different with
- 15 every processor.
- 16 Q. But it would be something to consider,
- 17 right?
- 18 A. Something for that processor to
- 19 consider, yes.
- 20 Q. All right. Are you familiar with the
- 21 term SKU?
- 22 A. No. I've seen it on some of the
- 23 documents, but --
- 24 Q. If I told you it was a stock keeping

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- 1 unit, would that mean something?
- 2 A. Stock keeping unit?
- 3 **Q**. Yes.
- 4 A. No.
- 5 Q. Okay. Do you interface with retailers
- 6 in your current job?
- 7 A. No.
- 8 Q. Did you interface with retailers in
- 9 your job in the market administrator's office?
- 10 A. No.
- 11 Q. So you don't know how they put stock
- 12 keeping units together to maintain inventory
- 13 compliance?
- 14 A. I don't know it, but my staff who
- 15 inspects dairy processing plants are familiar with
- 16 that, yes. That's one thing that they check on
- labels, when they inspect the processing plants.
- 18 Q. What do you mean?
- 19 A. Well, they check all the labels, not
- 20 only them, but they send them to Mr. Murray. And
- 21 it's not a violation if they have some milk that's
- 22 going to XYZ store that's on a pallet that's going
- 23 to ABC. But they -- they review it to see where
- 24 milk is being shipped to; just part of that

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- 1 inspection process.
- 2 Q. But what does that have to do with
- 3 SKUs?
- 4 A. Nothing, really.
- 5 Q. Okay. So when you're putting this rule
- 6 together, you didn't take into account the fact
- 7 that retailers have a limited number of SKUs that
- 8 they'll accept from a dealer?
- 9 A. No.
- 10 Q. Is there any flexibility in the rule
- 11 for small packages?
- 12 A. Small packages? You mean like pints
- 13 versus gallons?
- 14 Q. Half pints or pints.
- 15 A. No.
- 16 Q. They have to have the same font? They
- 17 have to have the language in the exact same format
- 18 that's prescribed?
- 19 A. A pint doesn't have to have the same
- 20 font as a gallon, as long as the disclaimer is
- 21 not -- less than a half was the claim, and less
- 22 than 7.5.
- 23 Q. So that is not an exception, though,
- 24 the way you just said it, right?

- 1 A. No. You said does it have to have the
- 2 same font. Are we talking about the same font on
- 3 a pint that's on a gallon?
- 4 Q. Same font size. So you just said they
- 5 have to have -- it has to be no less than 7 point
- 6 font.
- 7 A. Yes.
- 8 Q. And that's the same rule that applies
- 9 to a gallon container?
- 10 A. A gallon, yes.
- 11 Q. Okay. So there's no difference? Okay.
- 12 Never mind. Strike that.
- The director mentioned Smith Dairy as a
- 14 label that you brought up to him around the time
- 15 that this whole process for listening sessions was
- 16 being considered. What label were you referring
- 17 to?
- 18 A. It was on a gallon container, which had
- 19 huge font of 30 or more, "No rbST."
- 20 Q. And did it have other language on it?
- 21 A. Yes, it did.
- 22 Q. What did it have?
- 23 A. It had the disclaimer.
- 24 Q. It had the disclaimer?

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- 1 MR. PATTERSON: I think he answered
- 2 your question.
- 3 A. -- this is not their final label.
- 4 Q. Right. It's the --
- 5 A. It's the one that I -- okay. Yes.
- 6 They did send in a corrected label.
- 7 Q. A corrected label?
- 8 A. One that -- corrected to meet the rule.
- 9 Q. Okay. What under -- just languagewise,
- 10 take off the table any issue about size of font,
- 11 color, because this is black and white, all of
- 12 that. Languagewise, what was objectionable in
- 13 this?
- 14 A. There is no production claim. It's a
- 15 composition claim. "No Artificial Growth Hormone"
- 16 is a composition claim. And "Lactaid Farmers'
- 17 Pledge," doesn't say what they pledge.
- 18 Q. Okay. So if it said Lactaid farmers
- 19 pledge no artificial growth hormone, would that be
- 20 fine?
- 21 A. Pledge not to use artificial growth
- 22 hormone.
- 23 Q. What's the difference?
- 24 A. It's a production claim.

Lewis R. Jones

- 1 Q. So they can't just say Lactaid farmers
- 2 pledge no artificial growth hormone?
- 3 A. No. If the farmers pledge it -- we'd
- 4 have to take a look at that. We'd have to look at
- 5 that closely. It's really a nonissue, because
- 6 they've already given us a label that does apply.
- 7 Q. Well, I'm not asking for the Lactaid
- 8 label. I'm asking to understand --
- 9 A. If it just said -- strike the "No
- 10 Artificial Growth Hormone" at the top. If it says
- 11 Lactaid farmers pledge no artificial growth
- 12 hormones, we would probably not accept it. It's
- 13 not a production claim.
- 14 Q. Why wouldn't you accept it?
- 15 A. It's not a production claim.
- 16 Q. Because of the words "No Artificial
- 17 Growth Hormone"? You would accept it if it said
- 18 Lactaid farmers pledge not to use artificial
- 19 growth hormone, but you would not accept it if it
- 20 said Lactaid farmers pledge no artificial growth
- 21 hormone?
- 22 A. Well, if it's a farmer's pledge -- the
- 23 farmers pledge no artificial growth hormone. I'd
- 24 have to take that up with my staff. I don't -- I

- 1 don't look at it -- when they come in, I don't
- 2 look at them and say, okay, we're going to accept
- 3 that one. I put my staff together and if there's
- 4 some question, we'll discuss it, along with --
- 5 along with Mr. Murray.
- 6 But that one I'll have to -- if it's
- 7 farmers pledge no artificial growth hormones,
- 8 there's a good chance that we would accept it. If
- 9 it's a farmers pledge, then farmers do produce.
- 10 By stretching it, we would probably accept it,
- 11 okay?
- But if it just says "No Artificial
- 13 Growth Hormones" --
- 14 Q. If it said no artificial growth
- 15 hormones, our producers do not use artificial
- 16 growth hormones, would that be acceptable?
- 17 A. No, because of the part that says "no
- 18 artificial growth hormones." Strike that first
- part and we'd probably accept the second part,
- along with the disclaimer.
- 21 Q. And if it said -- okay. And if like in
- 22 Pennsylvania it said, "Lactaid's Farmers' pledge
- 23 no artificial growth hormone," and "no artificial
- 24 growth hormone" were in a bigger font, that

```
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 2
     County of Franklin: SS
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 4
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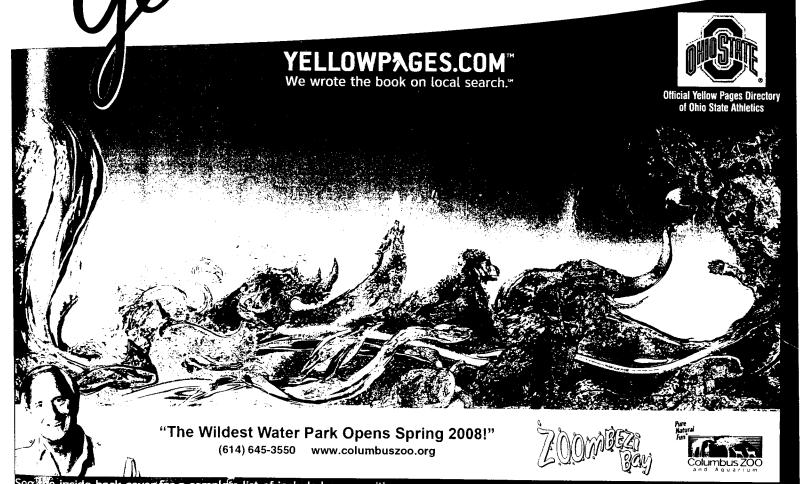


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Monsanto's recombinant bovine growth hormone (rbST)

... recombinant bovine growth hormone (bovine somatotropin or **rbST** product) in **No**vember 1993 after a comprehensive ... FDA determine the **safety and** efficacy of ... www.**monsantodairy.com**/faqs/fda_**safety**.html - <u>Cached</u>

Recombinant Bovine Somatotropin (rbST) Safety

... Agency's original conclusion that milk from cows treated with **rbST** is safe for human consumption. ... Food and Drug Administration's Review of the **Safety** of ... www.monsantodairy.com/about/human_safety/fda_cvmfeb.html - Cached

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The Center for Food Safety - rBGH / rBST

Organic and Beyond. National Organic Coalition. rBGH/Hormones. rBGH / rBST. Legal Actions ... Tell Congress to Support Labeling and Safety Testing of GE Foods! ... www.centerforfoodsafety.org/rbgh2.cfm - Cached

Cornel University - BST Fact Sheet

YES! Extensive studies of the **safety** of bST have been conducted world-wide and ... be labeled as "from cows not treated with **rbST**" **and** what does it mean? ... www.**cfsan.fda.gov**/~ear/CORBST.html - <u>Cached</u>

rbST Facts | Recombinant Bovine Growth Hormone

The Facts About **rbST** ... The development and use of **rbST** has been controversial. ... asserting the **safety and** efficacy of **rbST** – including scientific institutions, ... www.rbstfacts.org - <u>Cached</u>

Bovine somatotropin - Wikipedia, the free encyclopedia

... plausible" **safety** concerns for humans about the sale of **rBST** in Canada barring ... of Physicians and Surgeons of Canada Expert Panel on Human **safety** of **rbST** ... **en.wikipedia.org**/wiki/Recombinant_bovine_somatotropin - 73k - <u>Cached</u>

TED Case Study: Bovine Growth Hormone (rbST) and Dairy Trade

... Health and the American Medical Association have approved the **safety** of **rbST**.(3) ... and the UK Medicines Commission have approved the **safety**, quality, ... www.american.edu/TED/bst.htm - Cached

UPDATE ON HUMAN FOOD **SAFETY** OF BST

1999 CVM Update ... oral rbST based on serum antibody levels in the rats, and toxicity to the rats.

... about the safety of milk from rbST-treated cows. ... www.fda.gov/cvm/CVM Updates/BSTSAFUP.html - Cached

What is <u>rBST? - rBST Defined</u>

... five years, said officials "suppressed and manipulated data" in safety testsing was ared Saving Money food safety risks covered by FDA guidelines had not been ... whatisrbst.org - Cached

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Questions And Answers About bST From The United States Food And Drug Administration

FDA approved Monsanto Company's recombinant bovine growth hormone (bovine somatotropin or rbST product) in November 1993 after a comprehensive review of the product's safety and efficacy, including human food safety. The safety of milk from rbST treated cows was clearly demonstrated. Since marketing of Monsanto's product began in February, CVM has received numerous inquiries from consumers concerned about this product. The following are answers to some of the questions we have received on the product which is being marketed under the name of POSILAC®.

How does FDA determine the safety and efficacy of new animal drugs such as POSILAC?

In order for a new animal drug to be approved for marketing the U.S., the sponsor must establish that it is effective and safe. Effectiveness means that the drug does what the company claims (for example, increases milk production). Safety covers three main areas: safety of the food products to humans, safety to the target animal (the cow), and safety to the environment. In addition, companies must prove to FDA that they can consistently manufacture the drug to a specific potency and purity.

Drug sponsors must submit to their New Animal Drug Application (NADA) data to determine the safety and effectiveness of the drug product. In cases where data required by FDA to make decisions are not otherwise available, the drug sponsor is responsible for providing the data. The drug sponsor may conduct the study or may have the research performed by a contract laboratory. FDA has neither the legal authority nor the resources to do the drug testing on its own.

FDA takes a number of steps to monitor the reliability of data submitted to an NADA. Before sponsors conduct their studies, they usually submit study protocols to FDA. In this way, the FDA can comment on the adequacy of the studies and recommend any changes or additions that are necessary. Although the sponsors fund and monitor safety and effectiveness studies, the majority of the trials are conducted by independent scientists at universities, research laboratories, or commercial farms. FDA also has a Bioresearch Monitoring Program which allows FDA inspection of safety and effectiveness studies while they are ongoing. Finally, sponsors must submit their raw data to the NADA so that FDA can check the accuracy and completeness of the summary results that were derived and the statistical methods used.

Is the milk from cows treated with rbST any different from milk from untreated cows?

No. Milk from cows treated with POSILAC is not different from milk of non-treated cows. It has the same nutritional benefits as any other milk. It is safe for the consumer.

APP.III 0695

How do you know that rbST is safe for humans who consume meat and milk from treated cows?

FDA only approved POSILAC after concluding that its use poses no risk to human health. Cows produce bovine somatotropin in their pituitary glands. Thus, we have been naturally exposed to trace levels of bST in beef, milk, and other dairy products. Because it is a protein hormone, bovine somatotropin is broken down during digestion, which renders it biologically inactive and incapable of having an effect in humans. Intact proteins are not absorbed into the body. Even if injected into humans, bST has no effect. In the 1950s, studies were done to look at natural bST as a possible treatment for human dwarfism. The hormone had no effect on those treated. An additional assurance of safety is that heating, such as with cooking and pasteurization, inactivates bST that may be present in milk or meat. In addition to FDA, a panel of independent medical and veterinary experts at a National Institutes of Health (NIH) Technology Assessment Conference in December 1990, concluded that milk derived from cows treated with rbST is safe for human consumption. Also, the Office of Technology Assessment (OTA) released a report in May 1991 entitled U.S. Dairy Industry at a Crossroad: Biotechnology and Policy Choices. The report analyzes technologies, particularly bovine somatotropin, that would likely be available to the dairy industry in the 1990s. In the report, which was prepared at the request of Congress, OTA agreed with FDA's decision that food from cows treated with bovine somatotropin poses no additional risk to consumers. The World Health Organization (WHO) Joint Expert Committee on Food Additives in 1992 also confirmed FDA's conclusion that the food products from rbST-treated cows are safe for humans, as have the American Medical Association and the drug regulatory bodies of the European Union and other countries including Canada, Mexico, and the U.K.

What about the possibility that insulin-like growth factor 1 in milk from treated cows will lead to increased rates of breast cancer and other human health problems?

FDA and other scientific and regulatory bodies have thoroughly examined the safety of milk produced by rbST-treated cows and have concluded that it is safe. There is absolutely no possibility that the consumption of milk from rbST-treated cows could increase the risk of breast cancer. Insulin-like growth factor 1 (IGF-1) is a natural protein which mediates many of somatotropin's actions. It is required for normal growth and possibly health maintenance. IGF-1 is structurally and chemically similar to insulin and is normally present in most body tissues and fluids including human breast milk and saliva.

The consumption of dietary IGF-1 plays no role in either inducing or promoting any human disease, nor does it cause malignant transformations of normal human breast cells. Abnormally low levels of IGF-1 are associated with several disease conditions including dwarfism, malnutrition, osteoporosis and infertility. It has also been suggested that a decline in IGF-1 levels in human tissue causes many of the degenerative changes associated with aging.

Levels of IGF-1 in cow's milk and meat are very much lower than the levels found naturally in human blood and other body tissues. The IGF-1 occurs naturally in human breast milk at about the same concentration as that found in cow's milk. FDA has reviewed several comprehensive studies to determine if administering rbST in cows affects the IGF-1 content of their milk. These studies have demonstrated that rbST does not increase the IGF-1 content above levels normally found in milk of non-treated animals.

IGF-1 in milk and meat is not absorbed intact. Dietary IGF-1 in milk and meat is broken down in the gastrointestinal tract by digestion. Undigested IGF-1 is excreted in the feces.

The suggestion that IGF-1 in milk can induce or promote breast cancer in humans or premature growth stimulation in infants is scientifically unfounded. Milk from rbST-treated cows is safe for human consumption.

How can FDA be sure that mastitis caused by using rbST in cows will not lead to increased antibiotic use and antibiotic residues in milk?

Cows treated with POSILAC have a slightly increased risk of mastitis, a common infection of the udder, and antibiotics are often used to treat mastitis. However, FDA has concluded that the increased risk to human health posed by mastitis and the resulting use of antibiotics is insignificant. The effect of POSILAC treatment on the incidence of mastitis is much less than other factors, such as the season, age of the cows, and herd-to-herd variation. For example, the increase in mastitis incidence from winter to summer is at least nine times greater than the increase due to POSILAC treatment.

Another important factor is that therapeutic drugs, such as antibiotics for the treatment of mastitis, are to be used in food-producing animals only under approved conditions and with appropriate milk and meat withdrawal periods (as established by FDA) to ensure that food products are safe for human consumption.

Federal and State programs require milk to be tested for drug residues, and milk found to have unsafe levels of residues must be discarded. Further, producers responsible for violative residues are subject to severe regulatory sanctions.

FDA's Veterinary Medicine Advisory Committee and expert consultants met in an open public hearing in March 1993 to discuss the issue of increased mastitis in POSILAC-treated cows and a potential increase in the risk of antibiotic residues in milk. They concluded that the risk to human health was insignificant. Finally, Monsanto has agreed to an extensive post-approval monitoring program to ensure that the use of POSILAC in cows does not lead to an increase in the incidence of violative antibiotic residues in milk.

Why do you think the product is safe when it causes cow health problems?

FDA would not have approved the drug if there were serious risks to the health of the cows. The labeling for POSILAC, which includes precautions and side effects, provides direction to the farmers who use the drug. Such cautions are included on all drugs, and are based on data from pivotal studies submitted by the drug sponsors. These cautions alert farmers to potential problems that might occur with use of the drug. With this information, farmers can decide whether they will try the drug on their farm. If they decide to use the drug, they may use the labeling information to change their management practices, if possible, to help minimize problems associated with the use of the drug.

Cows using POSILAC may have small decreases in gestation length and birth weight of calves. However, this is not considered to be a serious problem, and actually may help make it easier for the cow to give birth. Health and growth of the calves from POSILAC and control cows was similar. In addition, other cow health problems that might be associated with the use of the drug are not considered by FDA to be serious health problems. Also, these problems did not occur at rates that would prohibit the use of POSILAC.

What about the increased "pus" in the milk from cows treated with rbST?

Some individuals are incorrectly using the word "pus" to refer to somatic cells in milk. FDA concluded that the milk somatic cell count (SCC) may increase in some herds when POSILAC is used. Somatic cells are always present in milk and consist of cells (such as epithelial cells, leukocytes, neutrophils, and macrophages) that are already present in the human body and blood. These cells are necessary to fight infection, and the increase noted in some POSILAC-treated cows likely reflects the slight

increase in mastitis incidence and mammary cells which slough off during infection. There are no health consequences associated with the consumption of SCC. Also, somatic cells themselves do not change the appearance of milk. The U.S. government imposes a limit on the maximum level of SCC permitted per dairy farm. However, this is not based on a human safety concern, but rather an economic concern. Increased levels of SCC in milk are associated with reduced cheese yields because enzymes released by somatic cells degrade casein in milk. Some dairy processors offer financial bonuses to farmers who produce milk with low SCC. Thus, there are substantial financial incentives for dairy farmers to maintain low SCC levels in their milk.

Why didn't FDA require Monsanto to develop a test to determine whether milk comes from treated cows?

FDA did not require Monsanto to develop such a test because the milk from cows treated with POSILAC has been determined to be safe for human consumption. Since there is no human food safety concern, FDA has no grounds on which to demand such a special identification test. While developing such a test is theoretically possible, it would also be useless for regulatory purposes.

Why aren't you requiring that milk and meat from treated cows be labeled as such?

FDA cannot require special labeling of products from cows treated with POSILAC because the Agency has concluded that it lacks a basis under the law to require special labeling of such foods. Milk from treated cows is the same as milk of untreated cows. However, voluntary labeling is permitted if it is truthful and not misleading. In response to requests from several State, industry, and consumer representatives, FDA has published interim Guidance on voluntary labeling of products from cows that have not been treated with rbST. This interim guidance was published in the Federal Register on February 10, 1994.

Why did the FDA approve this drug to increase milk production when we already have too much milk?

By Federal law, social and economic needs for a drug cannot enter into FDA's approval decision. However, in its budget reconciliation bill, Congress included a 90-day moratorium on the sale of rbST following FDA approval. During the 90-day period, the Office of Management and Budget (OMB) conducted a study to address these economic concerns.

In their report, "Use of Bovine somatotropin (rbST) in the United States: Its Potential Effects," OMB stated that income for individual farmers who use bST is likely to increase for both small and large farms. They also believed bST use would increase U.S. milk production by about one percent through Fiscal Year 1999. This would likely lead to slightly lower prices for milk, leading to declines in aggregate dairy farm income by about one percent over the same period. OMB stated that the lower milk prices from bST use are expected to contribute to higher Federal Government dairy price-support costs. Federal dairy price-support program costs are expected to increase by approximately \$150 million in the peak year, Fiscal Year 1996, and decline in later years. However, lower milk prices are expected to decrease costs for nutrition programs like Food Stamps and the Special Supplemental Food Program for Women, Infants, and Children (WIC). According to OMS, savings in the costs of Federal feeding programs could begin in Fiscal Year 1997, and could completely offset the increased cumulative costs of the Federal dairy price-support program over 10 years. Therefore, approval of animal drugs to improve production helps ensure a bountiful food supply for our children and grandchildren.

Why did FDA approve this drug for use in the U.S. when it is banned in Europe?

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The European Community placed a ban on the use of rbST on economic and political grounds. This had nothing to do with rbST safety. In January 1993, the Committee for Veterinary Medicinal Products of the European Union reaffirmed that food products from cows treated with rbST are safe for human consumption, and they recommended the approval of two rbST products based upon their review of all aspects of safety and effectiveness.





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For over 10 years, rBGH (recombinant bovine growth hormone), also known as rBST (recombinant bovine somatotropin), has been a staple in the dairy products consumed by Americans. Since these products are not labeled as containing rBGH / rBST, most consumers have no idea that a growth hormone



intended to induce dairy cows to be more productive is in much of their milk, cheese, and yogurt.

After approving the use of rBGH in 1993, the Food and Drug Administration has turned a deaf ear to the pleas of consumers, food safety organizations and scientists to reverse its approval of the hormone, or to simply require labeling of foods containing rBGH. Even a legal challenge by CFS could not force FDA to reexamine the health threats of rBGH. The FDA's decision stood despite regulatory bodies in both Canada and Europe rejecting the hormone due to numerous animal and human health concerns.

In cows treated with rBGH, significant health problems often develop, including a 50 percent increase in the risk of lameness (leg and hoof problems), over a 25 percent increase in the frequency of udder infections (mastitis), and serious animal reproductive problems, i.e., infertility, cystic ovaries, fetal loss and birth defects.

Because rBGH use results in more cases of mastitis, dairy farmers tend to use more antibiotics to combat the infections, the residues of which also may end up in milk and dairy products. These residues can cause allergic reactions in sensitive individuals and contribute to the growth of antibiotic resistant bacteria, further undermining the efficacy of some antibiotics in fighting human infections.

Furthermore, recent research has shown conclusively that the levels of a hormone called "insulin-like growth factor-1" (IFG-1) are elevated in dairy products produced from cows treated with rBGH. Canadian and European regulators have found that the FDA completely failed to consider a study that showed how the increased IGF-1 in rBGH milk could survive digestion and make its way into the

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Stop the Approximation Genetic Engine



Case 2:08-cv-00628-JLG-NMK Document 37 Filed 09/16/08 Page 80 of 157

intestines and blood stream of consumers. These findings are significant because numerous studies now demonstrate that IGF-1 is an important factor in the growth of cancers of the breast, prostate and colon.

CFS seeks to force the FDA to remove rBGH / rBST from the market through all available legal means. In 1999, CFS, joined by a number of other organizations, filed a legal petition with the FDA requesting that it remove from the market Monsanto's rBGH / rBST (trade name Posilac). In late 2000, the FDA announced that it was denying that petition. CFS will continue applying legal pressure on this important food safety issue.

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The Center for Food Safety

660 Pennsylvania Ave, SE, #302 Washington DC 20003 P: (202)547-9359, F: (202)547-9429 office@centerforfoodsafety.org ODA00613 Page 1 of 2

Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Wednesday, March 12, 2008 1:50 PM

Subject: Governor's Office Response

Respectfully Referred.

Not Acknowledged.

Sincerely,



77 South High Street, 30th Floor Columbus. Ohio 43215-6108 (614) 644-4357 Constituent Hotline (614) 466-9354 fax

Contact the Governor, click here.

Responses to this email address are not monitored.

Should you need additional assistance, please call the Constituent Hotline or visit the Governor's website to submit another inquiry.

This email and any response to it may constitute a public record and thus may be made available to anyone who requests it.

From: Steven Carter [mailto:Steven.Carter@Computer.Org]

Sent: Tuesday, March 11, 2008 11:42 PM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Steven Carter

Email: Steven.Carter@Computer.Org

Address: 111 Fallis Road

City, State ZIP: Columbus Ohio, 43214

Phone: 614-268-7097

Comments:

ODA's email system rejected my comments on the proposed regulations concerning the labeling of milk made without artificial hormones. I wish to share the comments with the Governor and request that they be forwarded on to the ODA. The current labeling requirements have served consumers well for fourteen years, since the introduction of artificial hormones that artificially increase the production of cow milk. The Governor's executive order requiring common sense in business practices should apply to this situation. Complicated and burdensome rules regarding the labeling of milk and milk products that are produced without rbST or rbGH are unnecessary.



rage 2 or 2

anti-free market, and ultimately anti-consumer because they artificially restrict the information consumers need to have to make purchasing decisions. The current FDA labeling regulations are more than sufficient. Following the Governor's executive order (2008 -04S) regarding common sense business practices and regulations; federally promulgated rules should be implemented as written unless there an Ohio specific public policy goal. If the rest of the country can understand what it means to have milk and milk products produced without artificial hormones then it is a safe conclusion that Ohio's consumers are smart enough to understand the same. Thank you for your time and consideration in this matter.

Response: No

Shy, Cindy

From: Governor Reply [Governor Reply@governor.ohio.gov]

Sent: Wednesday, March 26, 2008 9:08 AM

To: Jeremy Turner

Dear Mr. Turner:

Thank you for your recent letter regarding the way in which dairy products are labeled. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



77 South High Street 30th Floor Columbus. Ohio 43215 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here.

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This message and any response to it may constitute a public record and thus may be publicly available to anyone who requests it.

From: Jeremy Turner [mailto:turnerj12@yahoo.com]

Sent: Tuesday, March 25, 2008 10:44 AM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Jeremy Turner

Email: turnerj12@yahoo.com

Address: 5400 Watertower Ct Apt 211 City, State ZIP: Cincinnati Ohio, 45227

Phone: 513-333-7344

EXHIBIT 43

ODA02020

rage _ or 2

Comments:

In Sunday's Cincinnati Enquirer (3/23/08) I read a very concerning article titled "Kroger in milk lable battle". What concerns me most is that as a consumer I have the right to know what is and more importantly in this case IS NOT in my milk or any other product that I purchase. Kroger is simply wanting to do what is right -- inform the consumer of what they are purchasing. I am very disturbed that on February 7, 2008 you issued an emergency order to prevent Kroger from using their proposed new label. I realize the FDA approved the use of rBGH, but that doesn't mean that I want to consume products that contain it. Why is the government siding with chemical giant Monsanto as opposed to the consumer? I have a good guess....special interest groups.....\$\$\$\$. Please respond at your convenience. Thank you.

Response: Yes

ODA00442

Page 1 of 1

Samy, Raji

From:

Gabriella lacobone [iacoboneg@hotmail.com]

Posted At:

Friday, March 07, 2008 11:38 PM

Conversation: New law for milk labeling

Posted To:

Legal

Subject:

New law for milk labeling

To whom it may concern:

My name is Gabriella Iacobone and I'm currently a college student living in Columbus, Ohio. It has recently come to my attention that a new law is being discussed that would change the guidelines necessary for farmers in Ohio to label their dairy products rBST/rBGH-free. I wanted to add my voice to the body of concern regarding this matter.

I personally have made a strong commitment to purchasing products that are as natural and unadulterated as possible. I consider genetically-engineered hormones administered to meat and dairy animals to be an unhealthy addition to the food supply. Several studies have linked artificial hormones to early sexual development in children, as well as other problems. I understand there are concerns from dairy farmers who do use hormones as far as the rBST-free labeling, but as a consumer I value the right to make informed choices for myself.

That said, I strongly oppose the new law for labeling dairy in Ohio. Such regulations would make it much more difficult for small farms to market their truly rBST-free products, in effect making it impossible for consumers to be able to know if they are buying rBST-free dairy or not. I ask you to consider the importance of consumer choice regarding this law.

Thank you.

Gabriella Iacobone 4259 N Waggoner RD, Blacklick, OH 43004 (614) 855-7701

Shed those extra pounds with MSN and The Biggest Loser! Learn more.



*ODA00554 Page 1 01 2

Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Wednesday, March 12, 2008 1:47 PM

To: Carrie Sullivan

Subject: Governor's Office Response

Dear Ms. Sullivan:

Thank you for your recent letter regarding dairy product labeling. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely.



77 South High Street, 30th Floor Columbus, Ohio 43215-6108 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here

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This email and any response to it may constitute a public record and thus may be made available to anyone who requests it.

From: Carrie Sullivan [mailto:cmarie@zoominternet.net]

Sent: Wednesday, March 12, 2008 11:49 AM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Carrie Sullivan

Email: cmarie@zoominternet.net Address: 3381 Dalton Fox Lake Road

EXHIBIT TO THE SOLUTION OF SOL

Page 2 of 2

City, State ZIP: Orrville Ohio, 44667

Phone: 330-828-8491

Comments:

Dear Governor Strickland, I was diagnosed with Breast Cancer in November 2006 and have been monitoring my food choices closer for added hormones. You see, my breast cancer is hormonally driven so I appreciate the present labeling stating that my Skim Milk is 'RBsT Free'. I don't even begin to understand the conflict that is going on over this labeling issue, but why does it have to change? I need to know that the milk I drink has no added hormones! Besides, if cows make the hormone naturally, why do we need to add more artificially? I was talking with my Oncologist about this. Did you know these added injections to our food supply have shown that girls are beginning puberty at a younger and younger age? I would really appreciate the labeling to remain simple - RBsT Free. I just hope and pray, for my sake as well as all who fight Breast Cancer, that dairy suppliers are honest in reporting if their milk is truly free from additional hormones. For me, this is my life. Thank you for listening, Carrie Sullivan

Response: Yes

ODA00465

Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Monday, March 10, 2008 11:24 AM

To: Kim McCoy

Dear Ms. McCoy:

Thank you for your recent letter regarding the way in which dairy products are labeled. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



77 South High Street 30th Floor Columbus, Onio 43215 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here

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From: Kim McCoy [mailto:kmccoy@ameritech.net]

Sent: Sunday, March 09, 2008 8:52 AM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Kim McCov

Email: kmccoy@ameritech.net Address: 4734 Old Rt. 35 SE

City, State ZIP: Washington Courthouse Ohio, 43160

Phone: 740-335-0510



Page 2 of 2

Comments:

Governor Strickland, Please listen to consumers like me who do not want to buy milk with Recombinant Bovine Growth Hormone, known as rbGH or rbST. I want to KNOW that the milk I buy does not contain more hormones than nature intended. The ONLY way I can know this is if the producer of this product is allowed to say it is so. Thank you for listening and please pass this on to Mr. Boggs at ODA. Kim McCoy

Response: No

Samy, Raji

From:

csa@wowway.com

Posted At:

Friday, March 07, 2008 9:49 AM

Conversation:

Accurate Milk Labeling

Posted To:

Legal

Subject:

Accurate Milk Labeling

Agriculture Director Robert Boggs

Dear Agriculture Director Boggs,

Dear Governor Strickland:

As a mother of 3 young children and graduate of The Ohio State University's Food, Agricultural & Environmental Sciences program, I write to you today to strongly urge you not to ban dairy labels such as "no artificial hormones" or "rbST free" or "rbGH free." I carefully read and rely on food labels to make decisions about the food I purchase for my family.

I am concerned that the proposed rules will make it easier for dairy farmers to make untruthful claims on their product labels about genetically engineered growth hormones found in the products they sell.

All consumers have the right to know what is - and what is not - in the food they consume, and how and where that food is produced.

As my representative, whom I entrust to make my voice and others heard, please act to protect our right to know what's in our food and protect the health and well being of our children. Thank you, Carol Smith Allaire

Sincerely, Carol Smith Allaire 4501 Langport Road Columbus, OH 43220



Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Tuesday, March 25, 2008 12:04 PM

To: Shy, Cindy

Respectfully Referred

Sincerely,



77 South High Street 30th Floor Columbus. Ohio 43215 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here.

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From: Mitzie McElhaney,RN [mailto:mitziemc@hotmail.com]

Sent: Tuesday, March 25, 2008 10:09 AM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Mitzie McElhaney.RN
Email: mitziemc@hotmail.com
Address: 265 E. Schreyer Place

City, State ZIP: Columbus Ohio, 43214

Phone: 614-447-1152

Comments:

Dear Governor Strickland. Thank you for taking the time to review this information. After speaking with your aide this morning about the emergency dairy labeling ruling and the hearing I attended at the ODA on March 12th. I felt that it might be helpful as you make final decisions on this issue if you had links to some of what your aide and I discussed. So in this letter I hope to provide not a further argument against changing the dairy labeling ruling, as you know full well where so many of Ohio's consumers stand on this issue, but instead simply a list of links that will help you further understand exactly why Ohioans of all walks of life feel that this emergency dairy labeling ruling should be fully rescinded. Here is the information that is already in the hands of savy dairy consumers around the world, and these are the very reasons that rBGH use has been banned in over 30 countries, in Canada and the European Union. And it is the reason that further restrictions should not be placed on Ohio's sustainable dairy farmers who

3/31/2008

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choose not to inject their cows with rBGH, as they already meet such strict FDA guidelines which have been serving Ohio consumers well. The truth as you know is that the only dairy sales in Ohio that continue to rise are the dairies that produce rBGH-free milk. Ohio citizenry is educated and they are telling us all something and that is they want freedom of choice in knowing about and purchasing food products. If the label ruling makes it more restrictive, more difficult, more costly, for Ohio's dairy farmers to comply, it is not only the Ohio dairy industry who will suffer, but ultimately Ohio citizens and consumers. I hope you will take a look at these links, and please do not hesitate to contact me if there is anything I can do to provide clarification or further discuss this matter with you. 1. From the CANCER PREVENTION COALITION: http://www.preventcancer.com/consumers/general/milk.htm 2. From TruthOut, strongly worded, but still worth your time in seeing the full picture: http://www.truthout.org/issues_06/printer_030608HA.shtml 3. From the CONSUMERS UNION: http://www.consumersunion.org/pub/core_food_safety/005484.html Sincerely, and with Thanks, Mitzie McElhaney,RN 265 E.Schreyer Place Columbus, Ohio 43214 614-447-1152 Response: Yes

3/31/2008

Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Friday, March 28, 2008 8:19 AM

To: Kurt Szabo

Dear Mr. Szabo:

Thank you for your recent letter regarding the way in which dairy products are labeled. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



77 South High Street 30th Floor Columbus Ohio 43215 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here

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This message and any response to it may constitute a public record and thus may be publicly available to anyone who requests it.

From: Kurt Szabo [mailto:kszabo@insight.rr.com] Sent: Thursday, March 27, 2008 7:41 PM

To: Strickland, Governor Cc: Governor Reply

Subject: Governor Site Issues

Name: Kurt Szabo

Email: kszabo@insight.rr.com

Address: 14284 Jug Street

City, State ZIP: Johnstown Ohio, 43031

Phone: 614-855-2743

EXHIBIT 42

3/31/2008

ODA02018

Page 2 of 2

Comments:

If possible, please do not allow the ODA to prohibit food labels that make statements such as "rbST free" or "rbGH free" or "no artificial growth hormones." The industry says these statements confuse consumers, but I think Ohioans are smarter than the industry gives us credit for. Please prove them wrong.

Response: Yes

Suzanne T. Watkins-Martinez

16 E. Como Avenue, Columbus, OH 43202 614-267-5648/ e-mail: watkinsmartinez@hotmail.com

March 12, 2008

Ohio Department of Agriculture Attn: Legal Department 8995 E. Main Street Reynoldsburg, Ohio

Dear Sirs:

I write to you today as a consumer, wife and mother buying dairy products for my family from retail sources in Central Ohio.

I understand the labels on our dairy purchases may change in the near future. I am concerned that I may not be allowed to read on those labels whether Rbgh has been injected into the cows producing our Ohio dairy products.

Please consider the following as you craft your final labeling guidelines:

- 1) My family wants simple and clear labeling on the grocery items we purchase:
- 2) We want to know if Recombinant Bovine Growth Hormones have been injected into the cows producing the dairy products we buy;
- 3) If you want our continued trust and confidence, do not discount our ability to educate ourselves and make smart and healthy choices for ourselves and our families. We can and want to make these decisions for ourselves;
- 4) We want and will continue to buy Ohio dairy products if the above listed information can be offered by producers and protected by ODA.

Thank you for your serious consideration of my opinions. We and many other consumer families in our community will be monitoring your progress on this issue which is very important to us.

Sincerely,

Suzanne T. Watkins-Martinez



ODA00545

3-10-2008

Ohio Department of Agriculture 8995 East Main St Reynoldsburg Oh 43068

I write to ask you to to keep simple rules on our Dairy Labeling ie "rbGH-free". Technological advancements are a double edged sword, wonderful when they increase shelf life or product breakdown but sometimes providing exposure to unnecessary additives. Consumers have the right to know and decide how much, when and how much of a risk they take.

Simple package labeling is all we are asking for. Please respect our right to know and provide our families with peace of mind regarding this matter.

Thank you,

Donna Leone

Copy to the Honorable Governor Strickland

Pumber 14. SZB

ODA00366

Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Monday, March 10, 2008 2:09 PM

To: Karin Bergener

Subject: Governor's Office Response

Dear Ms. Bergener:

Thank you for your recent letter regarding dairy product labeling. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



77 South High Street, 30th Floor Columbus, Ohio 43215-6108 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here.

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This email and any response to it may constitute a public record and thus may be made available to anyone who requests it.

From: Karin Bergener [mailto:bergener@config.com]

Sent: Sunday, March 09, 2008 5:45 PM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Karin Bergener

Email: bergener@config.com Address: 8034 Limeridge Road

City, State ZIP: Ravenna Ohio, 44266

EXHIBIT

rage Lori

Phone: 330-298-0065

Comments:

Dear Ohio Department of Agriculture: I am an Ohio citizen. I am opposed to the proposed new labeling regarding rbGH in milk. I do not want to consume any dairy products from animals treated with hormones. There is no scientific evidence that the labeling approved by the FDA is misleading or in any way leads consumers to incorrect conclusions. The rule proposed by ODA is therefore unnecessary. Consumers have a right to know what is in their food and how it is produced. In addition to the consumer's right to be informed, we must consider the security of this country. Consolidation of our food supply is one of the gravest security dangers this country faces. Already, more than half of our food is imported. The proposed labeling will be a financial burden to small, independent dairies. Unreasonably burdensome regulations lead to the destruction of the industry regulated. With regard to our food supply, this will lead to greater imports and further consolidation. As political leaders from the ancient Romans to modern times (including Henry Kissinger) have said, "He who controls a country's food supply controls the country." Whether it is a foreign country, or simply a few large corporations, we will lose the independence of our food production to organizations that have no interest in the betterment of Ohio's citizens or economy. Please keep rbGH labeling simple: keep "rbGH-free" on Ohio's milk labels. Karin Bergener bergener@config.com

Response: No

ODA00307

Suzanne Garver

00009: 5198

5915 Linder Circle NE, Canton, Ohio 44721

February 16, 2008 09:09 AM

Ohio Dept. of Agriculture, Dairy Division OH

Subject: rBGH-free labeling is not "misleading" - please don't take away consumers' right to know

Dear Ohio Dept. of Agriculture, Dairy Division,

To: Ohio Dept. of Agriculture Dairy Chief Jones, and the Dairy Division.

CC: Governor Strickland Fax: (614)466-9354 Governor's Office Riffe Center, 30th Floor 77

South High Street Columbus, OH 43215-6108

I am writing to voice my opposition to apparent recent moves by the Ohio Department of Agriculture to restrict dairy producers from labeling milk as produced without recombinant bovine growth hormone. Many consumers object to this hormone, known as rBGH or rBST. I have a right to know if this artificial hormone was used in the production of the dairy products I buy, and I believe dairy companies should be able to inform customers of this fact.

The use of rBGH is concerning because it causes infections and other problems in cows. These infections lead to the use of more antibiotics, which could contribute to the major problem of antibiotic resistant bacteria. There are also many unresolved questions concerning the use of this artificial hormone and links to some types of cancers, particularly breast, prostate, and lung.

FDA approved the use of voluntary labels more than 12 years ago at the request of dairy companies seeking to respond to customer concerns over the use of the genetically engineered hormone. Earlier this year Monsanto, the company that makes rBGH under the trade name Posilac, pressured the FDA to restrict the use of labels identifying "rBGH-free" or "rBST-free" dairy products, but FDA rightly refused to do so. Ohio should be no different. Consumers want more information about the foods we buy and feed to our families - not less. rBGH-free labels are not "misleading," they fill an important gap in knowledge about how our dairy products are produced. In fact, an April 2007 Lake Research Partners' national survey shows that eight in ten adults (80%) feel dairy products originating from cows that have not been treated with rBGH should be allowed to be labeled as such.

I urge you to recognize the importance of food labels to consumers and producers, and not to restrict the use of rBGH-free labeling. Denying consumers information about how milk was produced leaves consumers without the information they need to make informed choices.

EXHIBIT 37

Jugares auer

Sincerely, Suzanne Garver 5915 Linder Circle NE Canton, Ohio 44721 ODA00330 rage roil



From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Thursday, February 21, 2008 8:23 AM

To: smolk@sbcglobal.net

Dear Ms. Molk:

Thank you for your recent letter regarding the way in which dairy products are labeled. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



"South High Street 30th Floor Columbus, Ohio 43215 6614; 644-435" Constituent Hottine 6614; 466-9354 faz Contact the Governor, click here.

Responses to this cinail address are not monitored. Should you need additional assistance, please call the Constituent Hotline or visit the Governor's website to submit another inquiry.

This message and any response to it may constitute a public record and thus may be publicly available to anyone who requests it.

Name: Stephen Molk

Email: smolk@sbcglobal.net Address: 500 Chilcote Ave

City, State ZIP: Columbus Ohio, 43202-316

Phone: Comments:

Please stop officials in your administration from eliminating an important food label. I want to know more about the food I eat, not less, and I want the information right there on the label. Dairies that want to inform me that they don't treat their cows with artificial hormones should be able to do so. Prohibiting



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such labeling is anti-competitive! Companies should be able to compete based on cost, quality, and production methods, but that means that buyers have to know the difference. Many people oppose the use of artificial growth hormones to increase milk production, and would buy an alternative milk if available. According to a June 2007 Consumers Union survey, 76% of consumers are concerned about the use of synthetic growth hormones to increase milk production and 88% support giving buyers choice through product labels. Monsanto and some dairy farmers say that these labels are misleading, and that there is no simple test to verify the presence of the synthetic hormone. But the Food and Drug Administration and the Federal Trade Commission investigated and determined that these labels are not, in fact, misleading. While it is correct that no simple, chemical test can verify the presence or absence of synthetic hormone, its use (or non-use) can be readily verified through record keeping and spot checks. Many claims on food labels are verified this way. It's un-American to prevent companies from telling buyers the truth about the special attributes of their product on the label. I have a right to know how my milk was produced, and dairies have a right to tell me this information. Please make sure that dairies in our state can clearly label their milk if it is produced without artificial hormones so that I can make an informed choice.

Response: No

Shy, Cindy

From: Governor Reply [Governor.Reply@governor.ohio.gov]

Sent: Monday, March 31, 2008 12:49 PM

To: Laura Krager

Dear Ms. Krager:

Thank you for your recent letter regarding the way in which dairy products are labeled. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



77 South High Street 30th Floor Columbus. Ohio 43215 (614) 644-4357 Consuluent Hotline (614) 466-9354 fax Contact the Governor, click here

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From: Laura Krager [mailto:kragerlaura@hotmail.com]

Sent: Sunday, March 30, 2008 5:51 AM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Laura Krager

Email: kragerlaura@hotmail.com

Address: 5417 Bassett Road

City, State ZIP: Atwater Ohio, 44201

Phone: 330-947-3785

EXHIBIT 37

3/31/2008

ODA02008

rage - or -

Comments:

Governor Strickland. I am very concerned about the milk labeling law passed that "levels the playing field". These hormones abbreviated as rBST and rBGH, are injected into cows to increase milk production, causing a number of problems with the milk, among them, raising levels of pus, antibiotic residues, and a cancer accelerating hormone called IGF-1. IGF-1 is a hormone stimulated by rBGH in the cow's blood stream, which is directly responsible for the increase in milk production. Now, if that does not make the milk different, then I don't know what does. I want the best for my children and If I have to pay more for the hormone free milk, then I will. I was hoping that the use of the hormone was going to become ban altogether. I'm sure Monsanto has a lot of lobbyists making sure that does not happen. I'm writing to tell you that I'm disappointed in this action that you have taken. This could very well effect how the rest of the country handles how they will deal with the situation. I pray they do not sign in similar legislation. Sincerely, Laura Krager

Response: Yes

From: Posted At: Conversation: Julia Rabe [romeozjul@yahoo.com] Friday, April 04, 2008 9:38 AM Proposed Rule 901:11-8-01 comments

Posted To: Administration

Subject:

Proposed Rule 901:11-8-01 comments

Julia Rabe 555 Harley Dr Apt 5 Columbus, OH 43202-1898

April 4, 2008

Director Robert Boggs 8995 E. Main St. Reynoldsburg, OH 43068

Dear Director Boggs:

I am contacting you regarding proposed rule 901:11-8-01 (Dairy Labeling), that would prevent consumers in Ohio from receiving truthful information about the regulated production practices used to produce certified organic milk and other dairy products.

I am a graduate student at Ohio State University. I have returned to the state after ten years between Indiana and Michigan. I also have both a personal history of digestive disorders and a family history of cancer, which make me extremely aware of what I am outting in my body. Due to these health concerns, I eat very limited preservatives and try to avoid hormone-treated animal products. As a scientist, I know that these treatments have a limited effect on the average person, but for people like me, they can be the final thing which will push my body over the I also feel that it is important for Ohio dairy farmers to be able to comply with USDA regulations for organic products. Not only would this ruling prevent out of state suppliers of organic milk from selling their product in Ohio, it would also prevent Ohio farmers from labeling their organic milk as such for export to other states. In an already difficult economic period, this could cripple many Ohio dairy farmers. Finally, I do not understand why this is an issue at all. People who want organic milk will still look for the names of the companies who have made organic milk in the past. People who are not as concerned will continue to buy the same milk they have always bought. This ruling would only make it more difficult for the buyer who prefers organic milk and the companies producing it. Please take both into consideration and follow the USDA and FDA rulings allowing, and requiring, this information.

Consumers not only care but also have a right to know about these regulated practices. Organic labels are controlled by OFPA as a matter of federal law. Any restrictions on the ability to communicate these federally regulated practices, such as the non-use of growth hormones, pesticides and antibiotics, will hurt organic farmers, producers and processors. More importantly the proposal will restrict consumers' right to truthful information about the milk produced by organic dairies.

Sincerely,

Julia Rabe

EXHIBIT SO

1

From: Rob Merkle [rpmerkle@hotmail.com]
Posted At: Friday, April 04, 2008 2:59 PM

Conversation: Organic labels are truthful - No 901:11-8-01

Posted To: Administration

Subject: Organic labels are truthful - No 901:11-8-01

Rob Merkle 5520 Heathrow Drive Powell, OH 43065-7969

April 4, 2008

Director Robert Boggs 8995 E. Main St. Reynoldsburg, OH 43068

Dear Director Boggs:

I am contacting you regarding proposed rule 901:11-8-01 (Dairy Labeling), that would prevent consumers in Ohio from receiving truthful information about the regulated production practices used to produce certified organic milk and other dairy products.

I am a resident of Powell, Ohio and the father of 3 year old twin boys who drink milk with every meal and snack. It is extremely important to my wife and I to know what we are feeding our children, and we choose to utilize organically produced foods in many cases. We do this not only to try to reduce the amount of non-natural substances that our boys ingest, but also because many organic farming practices are more earth-friendly than the parallel conventional farming practice. Whether or not rBST or rBGH are clinically proven to be harmful to humans or not, we, as responsible parents, want to know if such substances have been utilized in the production of the milk we give our children. There is no reason that the ability to make this choice should be taken away or impaired by manipulating the labeling of dairy products. Knowing this information is no less important to many consumers like us than is the nutritional information that must be published on all food products.

Consumers not only care but also have a right to know about these regulated practices. Organic labels are controlled by OFPA as a matter of federal law. Any restrictions on the ability to communicate these federally regulated practices, such as the non-use of growth hormones, pesticides and antibiotics, will hurt organic farmers, producers and processors. More importantly the proposal will restrict consumers' right to truthful information about the milk produced by organic dairies.

Sincerely,

Rob Merkle

From:
Posted At:
Conversation:
Posted To:

Dwight Ladd [climb2bhigh@yahoo.com] Tuesday, April 08, 2008 10:42 AM Organic labels are truthful - No 901:11-8-01

Administration

Subject:

Organic labels are truthful - No 901:11-8-01

Dwight Ladd 2970 Castlebrooke Ave. Columbus, OH 43026

April 8, 2008

Director Robert Boggs 8995 E. Main St. Reynoldsburg, OH 43068

Dear Director Boggs:

I am contacting you regarding proposed rule 901:11-8-01 (Dairy Labeling), that would prevent consumers in Ohio from receiving truthful information about the regulated production practices used to produce certified organic milk and other dairy products.

My name is Dwight Andrew Ladd and I am a voter and concerned citizen in Franklin County, OH. I make my consumer (and voting) choices based on educating myself about the issues I deem important. To deprive the citizens of Ohio, myself included, the right to make an informed choice is, I believe, neither fair to your constituency nor the role of state government. Additionally it will contradict existing Organic labeling laws which have been successful in creating uniform and verifiable standards in food production. I am concerned as well that contradicting the existing Organic standards will restrict interstate comerce and harm the Ohio ecomony. Please do not allow this proposed rule 901:11-8-01 to pass.

Consumers not only care but also have a right to know about these regulated practices. Organic labels are controlled by OFPA as a matter of federal law. Any restrictions on the ability to communicate these federally regulated practices, such as the non-use of growth hormones, pesticides and antibiotics, will hurt organic farmers, producers and processors. More importantly the proposal will restrict consumers' right to truthful information about the milk produced by organic dairies.

Sincerely,

Dwight Andrew ladd 614-777-5089

From: Posted At: Christopher Miller [c.j.miller@mindspring.com]

Saturday, April 05, 2008 8:58 AM

Conversation:

Consumers have a right to know (Proposed Rule 901:11-8-01)

Posted To: Administration

Subject:

Consumers have a right to know (Proposed Rule 901:11-8-01)

Christopher Miller 2781 Kingsbury Drive Rocky River, OH 44116-3219

April 5, 2008

Director Robert Boggs 8995 E. Main St. Reynoldsburg, OH 43068

Dear Director Boggs:

- I am contacting you regarding proposed rule 901:11-8-01 (Dairy Labeling), that would prevent consumers in Ohio from receiving truthful information about the regulated production practices used to produce certified organic milk and other dairy products.
- I live in Rocky River Ohio, work at NASA, and I spend a good deal of time while shopping reading the labels on the goods that I buy.
- I am concerned about the proposed rule because it seems to be completely contrary to my expectations for product labeling. Further, having read the testimony given by Michael Hansen before Ohio Dairy Board, I completely agree with his arguments. I see no problems with labels stating the presence or absence of artificial growth hormones and I would prefer to have that information available to me.

Thank you.

Consumers not only care but also have a right to know about these regulated practices. Organic labels are controlled by OFPA as a matter of federal law. Any restrictions on the ability to communicate these federally regulated practices, such as the non-use of growth hormones, pesticides and antibiotics, will hurt organic farmers, producers and processors. More importantly the proposal will restrict consumers' right to truthful information about the milk produced by organic dairies.

Sincerely,

Christopher J. Miller 440-356-9750

Ellis, Connie

From: John McGovern [johnmmcgovern@gmail.com]

Posted At: Friday, April 04, 2008 2:27 PM

Conversation: Proposed Rule 901:11-8-01 comments

Posted To: Administration

Subject: Proposed Rule 901:11-8-01 comments

John McGovern 7405 Herman Avenue Cleveland, OH 44102-2038

April 4, 2008

Director Robert Boggs 8995 E. Main St. Reynoldsburg, OH 43068

Dear Director Boggs:

I am contacting you regarding proposed rule 901:11-8-01 (Dairy Labeling), that would prevent consumers in Ohio from receiving truthful information about the regulated production practices used to produce certified organic milk and other dairy products.

Good Day:

My name is John McGovern and I both live and work in the city of Cleveland. Ohio has incredible resources in both farming and manufacturing, yet it seems we often limit our own potential with policies and laws that restrict potential growth industries. In the past we've had a severe limitation in the amount of resources allocated to lean/green manufacturing, advanced power generation, and sustainable/organic farming.

I believe Gov. Strickland is beginning to see the light in regards to how Ohio can become great again. That being said, why would we chose to move backwards and enable a law that eliminates a primary difference between organic and conventional dairies? Not only are we limiting growth in the 'exploding' organic market, but we are limiting a chance to educate Ohio consumers about how organic dairy farming benefits people/prosperity/planet. An analogy could be made between this potential new rule and the creation of a rule to limit consumer's knowledge regarding how/where their energy is produced.

Other than protecting big business, which already receive more than their fair share of protection, I don't understand how laws that reduce competition and limit consumer education and choice benefit anyone.

Consumers not only care but also have a right to know about these regulated practices. Organic labels are controlled by OFPA as a matter of federal law. Any restrictions on the ability to communicate these federally regulated practices, such as the non-use of growth hormones, pesticides and antibiotics, will hurt organic farmers, producers and processors. More importantly the proposal will restrict consumers' right to truthful information about the milk produced by organic dairies.

Sincerely,

John M McGovern 216.375.0450

ODA02002

Shy, Cindy

From: Governor Reply [Governor Reply@governor ohio.gov]

Sent: Thursday, April 03, 2008 9:13 AM

To: Shy, Cindy

Respectfully referred.

Not acknowledged.

Sincerely,



TED STRICKLAND GOVERNOR

77 South High Street. 30th Floor Columbus. Ohio 43215-6108 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here.

Responses to this email are not monitored. Should you need additional assistance, please call the Constituent Hotline or visit the Governor's website to submit another inquiry

This email and all responses to it may constitute a public record and thus may be made available to anyone who requests it.

From: Steven Hull [mailto:brenthull@sbcglobal.net]

Sent: Tuesday, April 01, 2008 6:57 PM

To: Strickland, Governor **Subject:** Governor Site Issues

Name: Steven Hull

Email: brenthull@sbcglobal.net

Address: 1415 Seneca Dr

City, State ZIP: Xenia Ohio, 45385-434

Phone: Comments:

I'm writing to ask you to rescind your emergency rule on milk labeling which is getting in the way of an important food label. I want to know more about the food I eat, not less, and I want the information right there on the label. Dairies that want to inform me that they don't treat their cows with artificial growth hormones should be able to do so. Executive Order 2008--03S makes

4/4/2008

EXHIBIT

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such labels illegal unless specific disclaimer language ("FDA has determined that there is no significant difference between milk derived from rbST-treated and non-rbST-treated cows") is added to the label in a specific location and in the same font, size and color of the main label claim. The Executive Order also makes labels such as "contains no artificial growth hormones" illegal. ***ALTHOUGH THERE MAY BE "no significance difference" AS DETERMINED BY THE FDA USING CURRENT TECHNOLOGIES. WE MAY EVENTUALLY FIND THE PRESENCE OF REMNANT rbST DOES POSE SOME HEALTH ISSUE. AS A 47 YEAR OLD IF THERE IS ANY KIND OF "DAMAGE" IT HAS ALREADY BEEN DONE. I AM CONCERNED ABOUT THE HEALTH AND WELFARE OF MY DAUGHTER. TRUE, I CANNOT ANTICIPATE EVERY PROBLEM AND PROTECT HER FROM EVERY DANGER, BUT I SHOULD BE ABLE TO MAKE REASONABLY INFORMED DECISIONS. MY DAIRY PURCHASES FOR MY DAUGHTER SINCE HER BIRTH HAVE BEEN DIRECTLY INFLUENCED BY THIS PARTICULAR ISSUE. PLEASE DON'T MAKE THE DAY-TO-DAY STUFF HARDER THAN IT ALREADY IS. PLEASE DO NOT ESTABLISH LAW THAT ULTIMATELY RESULTS IN THE WITHHOLDING OF POTENTIALLY VALUABLE INFORMATION. This Executive Order constitutes unnecessary bureaucratic meddling in the free market. The Food and Drug Administration said earlier this year that labels such as "contains no artificial growth hormones" or "from cows not treated with artificial growth hormones" are legal and not misleading. FDA has also stated that special disclaimer language is not required. No further rules are needed in Ohio. Many people prefer dairy products produced without the use of artificial growth hormones. According to a June 2007 Consumers Union survey, 76% of consumers are concerned about the use of synthetic growth hormones to increase milk production and 88% support giving buyers choice through product labels. Your Executive Order creates needless obstacles for dairies that want to let me know that their milk comes from cows not treated with artificial growth hormones. Other states don't have such requirements so labels on dairy product that are legal in other states would become illegal in Ohio, thus inhibiting interstate commerce. There is no reason for Ohio to waste time and money on further regulations. It's un-American to interfere with companies telling buyers the truth about the special attributes of their product on the label. I have a right to know how my milk was produced, and dairies have a right to tell me this information. Please make sure that dairies in our state can clearly label their milk if it is produced without artificial hormones, so that I can make an informed choice. Don't interfere in the marketplace by adding unnecessary bureaucratic obstacles to such labeling. Please rescind Executive Order 2008--03S. Response: No

4/4/2008

Page 1 of 2

Samy, Raji

From: Shy, Cindy

Sent: Tuesday, March 11, 2008 3:46 PM

To: Samy, Raji

Subject: FW: Governor's Office Response

Cindy Shy
Communications Office
Ohio Department of Agriculture
8995 E. Main Street
Reynoldsburg, OH 43068
614-752-9817

Fax: 614-466-7754

The content of this message is based solely on the information provided to the Ohio Department of Agriculture from the inquiry made in your original email and may not reflect facts of certain or unique circumstances of which we are not aware. Further the advice provided is general in nature and may not be applicable to your specific situation. Therefore, we recommend that you consult a professional in regard to the specifics of your question. WARNING: Computer viruses can be transmitted via the internet. The Ohio Department of Agriculture accepts no liability for any damage caused by any virus transmitted via the internet.

From: Governor Reply [mailto:Governor.Reply@governor.ohio.gov]

Sent: Tuesday, March 11, 2008 3:14 PM

To: Meghan Coil

Subject: Governor's Office Response

Dear Ms. Coil:

Thank you for your recent letter regarding dairy product labeling. I appreciate you taking the time to contact me about this matter.

I have forwarded your letter to the Department of Agriculture and I have asked that your concern be reviewed and addressed as promptly and thoroughly as possible.

Thank you again for taking the time to write, and please feel free to contact my office in the future.

Sincerely,



77 South High Street, 30th Floor

ODA00415

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Columbus, Ohio 43215-6108 (614) 644-4357 Constituent Hotline (614) 466-9354 fax Contact the Governor, click here.

Responses to this email address are not monitored.

Should you need additional assistance, please call the Constituent Hotline or visit the Governor's website to submit another inquiry.

This email and any response to it may constitute a public record and thus may be made available to anyone who requests it.

From: Meghan Coil [mailto:meghancoil@yahoo.com]

Sent: Monday, March 10, 2008 4:42 PM

To: Strickland, Governor **Cc:** Governor Reply

Subject: Governor Site Issues

Name: Meghan Coil

Email: meghancoil@yahoo.com

Address: 24 Glendale St.

City, State ZIP: Cincinnati Ohio, 45216

Phone: 513-706-3090

Comments:

Dear Governor: I am writing to express my support of absence labeling. As a consumer, I demand to know what is in the food I eat. I have every right to make my food choices based on whether or not synthetic hormones have been used to produce it. Monsanto claims that there is no evidence that milk produced with rbGH is harmful, but I prefer to play it safe, as do millions of other consumers. If Monsanto is worried that their product has a bad reputation, that's their problem, not mine. Even if rbGH is not harmful to humans, I may wish to avoid it for other reasons. This is my prerogative. It is criminal to cause me to consume a product I prefer to avoid by denying me information about it. Farmers who don't use rbGH should be commended for their timely and savvy response to consumer demand, not punished for threatening Monsanto's bottom line. Please act in the public interest: please preserve the consumer's right to know how her food has been produced. Please preserve "rbGH-free" labeling. Thank you, Meghan Coil Cincinnati, OH

Response: No



Dairy labeling restrictions. Not the same old form letter, either

Page 1 of 1

Samy, Raji

From: Jone

Jones, Lewis

Sent:

Wednesday, March 12, 2008 7:23 AM

To:

Samy, Raji

Subject: FW: Written1

From: melgrubb@live.com [mailto:melgrubb@live.com]

Sent: Tue 3/11/2008 8:30 PM

To: Jones, Lewis

Subject: Dairy labeling restrictions. Not the same old form letter, either

Ohio Dept. of Agriculture, Dairy Chief Lewis R. Jones, R.S. OH

Dear Ohio Dept. of Agriculture, Dairy Chief Jones, R.S.,

To: Ohio Dept. of Agriculture Dairy Chief Jones, and the Dairy Division.

CC: Governor Strickland's Office Fax: (614)466-9354 Governor's Office Riffe Center, 30th Floor 77 South High Street Columbus, OH 43215-6108

I'm sure you have plenty of copies of the "sample letter" pertaining to this issue, so I won't send you another one. Instead, I'll just say that consumers have the right to know what is or isn't involved in the production of their food. If my cheese wants to wear a label proclaiming that it was made without moon rocks then so be it as long as it's factual. Whether rGBH does or does not make a difference to the resulting milk may not matter at all to someone who is more concerned with the treatment of the animals. The willingness to fill an animal with artificial drugs to stimulate their milk production tells me a lot about that farmer. It tells me that the well being of the cows takes a back-seat to the bottom line, and that is not something I want to support.

The market has the right to decide what practices it wants to support, whether there is scientific evidence backing up their perceived differences or not. Even if consumers are wrong about something, it's their right to be wrong. The dairy industry can do what they want to try to educate the public and convince them that their way is best, but they shouldn't be allowed to simply keep people from being able to tell the difference.

Mel Grubb II

Sincerely, Melvin Grubb 1074 E. Dunedin Rd. Columbus, OH 43224

cc;

Governor Ted Strickland



ODA00512

ODA00429

Samy, Raji

From: Posted At: Tom Rapini [tom@tingsys.com] Friday, March 07, 2008 9:50 PM

Conversation:

Keep it simple, keep rBGH-Free labels!

Posted To:

Legal

Subject:

Keep it simple, keep rBGH-Free labels!

Dear Governor Strickland and Director Boggs, Governor Strickland, Director Boggs,

It is a sad testimony to the power of industrial lobbies that a free society like ours would even consider telling farmers and/or food producers that they CANNOT label what ingredients are NOT in their product.

Certainly they should continue to be required to list all ingredients as they have been. But if they want to say their milk does not contain artificial growth hormones, they should be allowed to do so, just as many products today are labeled "sugar free", "no artificial color", "fat free", etc.

The dairy industry lobbyists suggest that this labeling implies something is unhealthy with rBGH when used to increase milk production. First, there is inconclusive scientific evidence that this may be true. Second there definitely are MORAL reasons to want to avoid rBGH, as it clearly has harmful long term effects on the cows treated with it. Third, there are social and moral reasons for consumers to want to be aware and perhaps opposed to the increasingly industrialized and chemicalized form of agriculture practiced in this country. And fourth, following through with their warped logic, one would have to conclude that other labels regarding sugar, color, or fat also imply there is something wrong with them and therefore THOSE labels should be disallowed also.

I am writing to oppose your proposed rule for labeling milk in Ohio. As a consumer, I feel that the proposed rule creates too many barriers for labeling milk that has not been treated with artificial growth hormones.

Keep it simple by sticking with the federal labeling rules that have worked just fine for the last 14 years.

Thank you, Tom Rapini

Tom Rapini 5947 Hopkins Rd. Mentor, OH 44060



Original Image of this Document (PDF)

2000 WL 33980809 (C.A.2) (Appellate Brief) For opinion see 272 F.3d 104

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William H. SORRELL, As Attorney General of the State of Vermont, John Kassel, Vermont Agency of Natural Resources, Defendants - Appellants.

No. 99-9450 May 5, 2000.

On Appeal from the United States District Court for the District of Vermont

Brief of Appellee National Electrical Manufacturers Association

Geoffrey W. Crawford, O'Neill, Crawford & Green, P.C., 159 Bank Street, P.O. Box 5359, Burlington, VT 05401, (802) 865-4700, Steven J. Rosenbaum, Anthony J. Vlatas, Covington & Burling, 1201 Pennsylvania Ave., N.W., Washington, D.C. 20004, (202) 662-6000

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*1 STATEMENT OF THE ISSUES

- 1. Was it clearly erroneous for the district court, following a three-day preliminary injunction trial, to make the factual findings that the challenged Vermont labeling requirements regulated conduct outside the State's borders, interfered with the ability of other states to impose their own regulations, and imposed burdens on interstate commerce that outweighed the benefits achieved in light of substantially less burdensome alternatives?
- 2. Was it clearly erroneous for the district court to make the additional factual findings that the Vermont labeling requirements did not directly advance the State's interests and were more extensive than necessary, thus giving rise to a First Amendment claim?
- 3. Did the district court act within its discretion in finding that plaintiff/appellee National Electrical Manufacturers Association (NEMA) had established irreparable injury, because the Vermont labeling requirements would impose very substantial *2 costs upon its members and the Eleventh Amendment would prevent recovery of these costs from the State?
- 4. Did the district court act within its discretion in finding that NEMA had established irreparable injury, because the Vermont labeling requirements would violate its members' First Amendment rights and such violations are per se irreparable?

5. Did the district court abuse its discretion in refusing to permit the State to rely upon affidavits of witnesses who failed to appear at trial, given that (a) the State never sought to preserve and present their testimony by way of deposition, (b) the State did not arrange to have these witnesses testify by video conference although it did so for another witness with the Court's permission, and (c) the State had refused the Court's offer to postpone the trial if the State would agree to postpone the effective date of the labeling statute?

*3 STATEMENT OF THE CASE

Mercury-containing lamps ("lamps"), such as the familiar fluorescent light bulb, are energy efficient alternatives to incandescent lighting, and their use results in a substantial net reduction in mercury emissions to the atmosphere. Lamps sold in Vermont (and elsewhere in the United States) are manufactured at more than sixty facilities scattered across four continents. The State of Vermont is the only jurisdiction in the entire world that has purported to establish the requirements under challenge here, namely, that mercury-containing lamps be so labeled, and that their packaging state that in Vermont, mercury-containing lamps may not be disposed in the trash but must either be recycled or disposed as a hazardous waste.

The district court found, and the State does not dispute, that the Vermont labeling requirements would as a practical matter require the eleven domestic and foreign lamp manufacturers with sales in Vermont to *4 re-tool their production and packaging processes at all sixty of their worldwide facilities with sales in Vermont and include the Vermont-required product and packaging labels on the billions of lamps those facilities supply throughout the world. The district court also found, after the receipt of copious testimony and the evaluation of witness credentials and credibility, that alternative, more effective, non-intrusive means exist by which Vermont could achieve its goal of informing consumers and other users of the fact that these lamps contain mercury and of the State's unique lamp disposal requirements.

The district court concluded that these facts established a likelihood of success on NEMA's Commerce Clause claim under the Pike test, and its First Amendment commercial speech claim under Central Hudson. Moreover, it found that the injuries caused by the implementation of the labeling requirements would be irreparable, because the Eleventh Amendment bars NEMA members from recovering damages for the financial and *5 other injuries they would suffer, and because First Amendment violations are per se irreparable. The district court accordingly granted NEMA's motion for a preliminary injunction against the Vermont labeling requirements.

STATEMENT OF THE FACTS

A. Mercury-Containing Lamps.

Three kinds of lamps contain mercury: "linear fluorescent lamps", the familiar elongated, cylindrical lamps widely used in retail, office, industrial and residential locations; "compact fluorescent lamps", which are similar in size and direct replacements for conventional incandescent bulbs; and "high intensity discharge (HID) lamps", which are used in commercial and industrial settings and are especially energy-efficient. 72 F. Supp.2d at 449, 452; see photographic representations at Supplemental JA 703-05.

These "[m]ercury-containing lamps ... are more energy-efficient than regular incandescent bulbs, thereby reducing needed energy production and the *6 emission of pollutants into the environment." 72 F. Supp.2d at 451. Under normal operating conditions they provide the same lumens (light energy) at between one-fourth and one-fifteenth the watts (power consumed) as an ordinary incandescent bulb. (JA51, 346). Because these lamps reduce the need for power generation, which itself emits mercury into the atmosphere, their use as replacements for incandescent bulbs results in more than a *six-fold reduction* in net mercury emissions, irrespective of the method of spent-lamp

disposal. (JA52, 347); see also 72 F. Supp.2d at 454 ("Power plants, especially those which burn coal, emit most of the mercury currently making its way into the environment.")

Mercury is essential to the efficient operation of these lamps; all known substitutes would lower their efficiency by 60-70% and make them little better than regular incandescent lamps. (JA52). Lamp manufacturers have, however, succeeded in reducing substantially the amount of mercury in their products; *7 the amount contained in the most popular lamp has on average been reduced 75% since 1985. (JA52-53, 311).

Due to their energy efficiency and pollution-reducing qualities, the United States Environmental Protection Agency has made the use of fluorescent lamps a major element of the United States' global climate change efforts. (JA52). All federal agencies are strongly encouraged in their use, as is private industry. (JA52, 362-63).

The United States government estimates that the disposal of mercury-containing lamps accounts for a very small percentage of domestic mercury emissions- approximately half a percent. (JA361-62); see also 72 F. Supp.2d at 454 (the portion of mercury emissions that would be addressed by Vermont's lamp labeling requirements is "very small"). The federal government resquires that certain high volume users either recycle certain of these lamps or dispose of them as hazardous waste. (JA 59-60). However, no federal disposal obligations are imposed upon smaller commercial or *8 industrial users, or upon any households. Id. Nor, with two exceptions, do any states impose such a household requirement. The two exceptions are Minnesota, where the utilities pick up spent lamps, and Vermont, which has recently imposed a requirement that all its citizens either recycle their lamps or dispose of them as hazardous wastes. (JA60-61).

B. Lamp production and sale.

Approximately 1.1 million mercury-containing lamps are sold each year in Vermont, 72 F. Supp.2d at 452. These represent less than one quarter of one percent of the mercury-containing lamps sold in the entire United States, and less than one sixteenth of one percent of worldwide sales. (Supplemental JA621). But because lamps are produced in mass quantities and transported and sold worldwide, eleven different foreign and domestic companies manufacture mercury-containing lamps that are sold in Vermont (and elsewhere). 72 F. Supp.2d at 452.

*9 Lamp manufacturers make a tremendous variety of mercury-containing lamps, which vary by length, wattage, and a host of other factors. (JA12-15). To be precise, more than 4800 different varieties of mercury-containing lamps are available for sale in Vermont(and other states). 72 F, Supp.2d at 452.

As the district court found, "lamps [sold in Vermont] are manufactured in a variety of places worldwide, including Europe, Asia, and South America," 72 F. Supp.2d at 454. Uncontested trial evidence demonstrated that approximately 60 plants, located in countries ranging from Chile to Singapore, and from Poland to Taiwan, produce lamps that are sold in Vermont, as well as elsewhere in the United States and around the world. (JA249-52, 56-57). (A map depicting specific NEMA member plant locations with sales in Vermont is found at Supplemental JA616.) Approximately 196 separate production lines are utilized in these plants to manufacture these lamps. (JA254-56). Only fourteen of these sixty plants are located in the *10 United States (and none in Vermont). (JA56-57, Supplemental JA 616).

C. The Vermont Labeling Requirements.

The Vermont labeling statute at issue here was enacted in April 1998 and amended in June 1999, and provides in pertinent part:

Effective March 1, 2000, a manufacturer or wholesaler may not sell at retail in this state, to a retailer in this state, or for use in this state, and a retailer may not knowingly sell, any of the following items

at retail if they contain mercury added during manufacture, unless the item is labeled. The label must clearly inform the purchaser or consumer that mercury is present in the item and that the item may not be disposed of or placed in a waste stream destined for disposal until the mercury is removed and reused, recycled, or otherwise managed to ensure that it does not become part of solid waste or wastewater. Primary responsibility for affixing labels required under this section shall be on the manufacturer, and not on the wholesaler or retailer... Items to be labeled are: ... A lamp.

See <u>Vt. Stat. Ann. tit. 10, § 6621d(a)</u> (Vt.Br. App. A001). Violation of this statute is punishable by a criminal penalty not to exceed \$25,000 or imprisonment ***11** for not more than six months, or both. See <u>Vt. Stat. Ann. tit. 10 § 6612</u>.

The Agency's implementing regulations largely mirror the language of the statute, except that they specifically require that the "label must be clearly visible and legible to consumers prior to purchase of the product"; the "label must be located on a surface of the product that is visible during installation and removal;" and "[f]or labels affixed to products, the required words or symbols must be printed, mounted, molded or engraved on the surface of the product using materials sufficiently durable to remain legible for the useful life of the product." See Vermont Solid Waste Management Rules, § 6-803(b)(Vt.Br. App. A003-004). Given the requirement that the product itself be labeled, and that labeling be visible prior to the time of purchase, both the lamp and its packaging would have to be labeled.

As the District Court found, 72 F. Supp.2d at 453, and the State concedes (JA483), this is "a marking *12 which no other state or nation requires." Minnesota, the only other state in the nation that requires households to recycle or dispose of lamps as hazardous waste, does not impose any labeling requirements on lamps. Minnesota Waste Management Act, § 116.92(3).

The Vermont labeling statute required that lamp manufacturers submit to the Secretary of the Agency of Natural Resources no later than October 1, 1999, a "labeling plan" demonstrating how the manufacturer intended to comply with the Statute and implementing rule. See Vt. Stat. Ann. tit. 10, § 6621d(a). Lamps and packages manufactured after March 1, 2000 would have to be labeled. Id.

The implementing regulations also provided that the Secretary could administratively authorize alternative labeling if a manufacturer submitted a written request documenting that a product or class of products could not reasonably be labeled to comply with the regulation's requirements. See Vermont Solid Waste Rules, \S 6-803(c)(1). Pursuant to that section, NEMA *13 requested that in lieu of labeling lamps or their packaging:

- 1. Lamp manufacturers would provide retailers and wholesalers point of sale signs to be posted where lamps are sold. The signs would inform consumers of the fact that the lamps contain mercury and that Vermont law requires that they not be put in the trash, but be recycled or disposed as hazardous waste.
- 2. Lamp manufacturers would provide their wholesalers and distributors printed information sheets regarding the presence of mercury in their lamps and of Vermont's lamp disposal requirements. These printed information sheets would be provided to Vermont office buildings, businesses, contractors, and other commercial and industrial users of lamps.
- 3. Lamp manufacturers would on a routine basis include on their invoices to wholesalers and distributors information regarding the presence of mercury in their lamps and Vermont's lamp disposal requirements. That information could be provided in *14 turn by those wholesalers and distributors in their own invoices to Vermont office buildings, businesses, contractors and other commercial users as an ongoing refresher regarding the state's lamp disposal requirements.
- 4. Lamp manufacturers would develop community information regarding mercury-containing lamps, and the Vermont disposal requirements. That information would be provided to all Vermont communities on an ongoing as-requested basis, for distribution to the citizens of Vermont. (JA227-29,

53-55).

The Agency rejected this offer. The Agency instead demanded that manufacturers not only engage in the foregoing acts, but also the following:

- 1. All mercury-containing lamps must be labeled with the symbol "Hg" in a circle.
- 2. The packaging in which lamps are sold at retail would have to be labeled with an explanation that the "Hg" in a circle on the lamp meant that it contained mercury, and with the statement "If Purchased *15 in Vermont-Don't Put in Trash-Recycle or Dispose of as Hazardous Waste." (JA230-31, Supplemental JA607; JA55). [FN1]

FN1. For reasons that NEMA cannot discern, the State now argues that the district court somehow erred in basing its evaluation upon the State's actual demands as described above, and should instead have rendered an advisory opinion on the alas tract question now put forward by the State of "whether the agency can require any label at all, whether it be the full text required by the statute or an agreed upon alternative, such as a symbol, phrase, or sentence." Vt.Br. 33-34. Indeed, the State remarkably represents to this Court that "[a]s a matter of law, Vermont cannot require NEMA members to label their products with an 'Hg' in a circle." Vt.Br. 32. But that is precisely what the State had purported to do, and at the time it flatly represented that "the Agency's suggested approach complies with Vermont law and rules." (JA92). The District Court properly based its opinion upon the State's actual demands.

D. The Impact of the Labeling Requirements.

As was found by the district court-and is not disputed by Vermont-the only way manufacturers could comply with the State's labeling requirements would be to re-tool their manufacturing and packaging operations at each of the 60 worldwide plants that make lamps some of which were sold in Vermont. The labeling would have to appear on the billions of lamps and packages *16 manufactured at these plants and sold around the world. Moreover:

- a) Lamp manufacturers lack the ability to put the required label on the lamp at any later point than the manufacturing plant. In order to achieve legibility and durability, all labeling appearing on a lamp is fired into the lamp as part of the manufacturing process. (JA24).
- b) Lamp manufacturers also lack the ability to put the Vermont-required labels on the packaging at any later point than the manufacturing plant. Individually-packaged lamps are put into sealed boxes before they leave the place of manufacture. The boxes themselves are often shrink-wrapped. (JA24).
- c) Even leaving aside these packing methods, and regardless of whether the purchaser is a commercial/industrial customer, an original equipment manufacturer, or an individual consumer, the distribution systems utilized by lamp manufacturers make it impossible for a manufacturer to know where any *17 particular lamp or group of lamps will be sold at the time those lamps leave the manufacturers' control. [FN2] The District Court explicitly found that "[i]t is impossible to predict whether any particular lamps will eventually end up on a particular retailer's shelf either in Vermont or anywhere else in the United States." 72 F. Supp.2d at 452. This is a fact conceded by the State. (JA506-07).
 - FN2. See JA24-28 for a detailed description of the lamp distribution system, which is graphically depicted at Supplemental JA618-20.

Accordingly, the district court found that "it is virtually certain that any manufacturer which plans to sell lamps in Vermont will have to label all lamps it produces to comply." 72 F. Supp.2d at 452. Thus, the legal requirements of a state that represents less than one-quarter of one percent of domestic

lamp sales, and less than one-sixteenth of one percent of worldwide sales, would dictate worldwide lamp labeling requirements.

*18 The District Court found that the costs that manufacturers would have to incur to comply with Vermont's labeling requirements would be "great" and "substantial" and that it was not necessary (given the equally effective alternatives that exist) to credit any particular cost estimate in order to resolve in the manufacturers' favor the ultimate question of whether they were entitled to a preliminary injunction. 72 F. Supp.2d at 453-54. The evidence established that manufacturers' costs of labeling the lamp and the packaging would be approximately \$9.2 million. (JA29-31). [FN3] To put this figure in context, the average lamp wholesales for less than \$2.50 (JA237), and with approximately 1.1 million lamps sold in Vermont each year, labeling costs would be nearly four times greater than total revenues. (JA282).

FN3. This cost figure assumed that the only labeling required on the lamp itself is the "Hg" in a circle. (JA268). Were the State to require manufacturers to inscribe the lamp with the full language of the Vermont statute - "If Purchased in Vermont - Don't Put in Trash - Recycle or Dispose of as Hazardous Waste" -the costs would at least double and perhaps triple. (JA274, 280, 284).

*19 The only conceivable option for a manufacturer (beyond the possibility identified by the District Court of not selling lamps in Vermont at all, see 72 F. Supp.2d at 453) would be to make specially labeled lamps and packages for sale in Vermont only. 72 F. Supp.2d at 453-54. But this option was correctly deemed by the District Court not to be viable "as a practical matter," 72 F. Supp.2d at 452 (not listing this among the practical alternatives), given that lamp manufacturers would have to undertake special production runs of labeled lamps and packages for sale in Vermont only, create new storage space for labeled products(to be distributed and sold in Vermont), and somehow induce their wholesalers and distributors to carry these products. (JA33-37). Producing and handling specially labeled products for sale in Vermont would result in a one-time cost of \$13,122,071, and recurring annual costs of approximately \$16,353,404 *20 (JA36), both of which dwarf the total gross revenues derived from lamp sales in Vermont. (See p. 18 above).

E. The Impact of Federal, State and Foreign Legal Requirements.

These substantial cost implications and worldwide impacts are only part of the problem. The discussion until this point has pre-supposed that lamp manufacturers could, at least on a theoretical level, comply with the Vermont labeling requirements by modifying their equipment to include the required language on all lamps and lamp packages they make. But in fact, there are significant legal impediments to their doing so.

Vermont would require manufacturers to label the lamps and packages with the symbol "Hg" in a circle, state that this meant that the lamp contains mercury, and state further that the lamp may not be discarded but must be recycled or disposed as hazardous waste. But in enforcing the Federal Trade Commission Act, 15 U.S.C. § 41 et seq., the Federal Trade Commission (FTC) forbids manufacturers from using *21 either a recycling claim or a "please recycle" request unless recycling facilities are available to a substantial majority of consumers or communities where the labeled product is sold. See FTC Guides, 16 C.F.R, § 260.7(d) (1999) (Supplemental JA712). With the exception of Minnesota (where the electric utility provides such services), and a few communities scattered throughout the country, the District Court found that household lamp recycling programs and facilities do not exist. 72 F. Supp.2d 452 & n.2; JA365-66. Under these circumstances, it would be unlawful for lamp manufacturers to place any unqualified recycling claim or request on lamps or packaging sold anywhere other than Vermont or Minnesota. (JA62, 366-67, 381-82).

Vermont purports to overcome the limitations imposed by the FTC Guides by requiring that the packaging label state that it is "in Vermont" that lamps are not to be put in the trash, but to be recycled or disposed of as hazardous waste. But this *22 additional language exacerbates, rather than alleviates, the conflict with federal law and the law of other states.

Many if not most purchasers would reasonably assume from this language that they can place lamps in the trash everywhere except Vermont, because the label identifies Vermont alone as the state where users cannot do so. But this is not at all true. (JA382-84, Supplemental JA625). As a result of the federal Resource Conservation and Recovery Act, "large quantity generators" and "non-exempt small quantity generators" cannot place lamps in the normal waste stream in any state(unless the lamps meet certain prescribed requirements). (JA368-74, Supplemental JA625, JA59-60). As a result of individual state law, small quantity generators in at least ten states cannot do so either. (JA60-61). In Minnesota, no one can. (JA60). In short, the Vermont label conveys a disposal message that run counter to the legal requirements of the federal government and other states.

*23 Conversely, some purchasers may reasonably read the Vermont label to prohibit lamp disposal in the trash in all states. As the District Court found, "[i]t is apparent that labeled bulbs which find their way to jurisdictions other than Vermont will cause confusion in that they identify the product as a hazardous waste which must be recycled." 72 F. Supp.Zd at 452. This is a false message, because in all other states except Minnesota, many users, including all household users, can dispose of mercurycontaining lamps in the normal waste stream. (Supplemental JA625, JA.58-61, 368-74).

F. There Are More Efficient and Effective Alternative to Labeling Lamps and Packages.

Vermont's labeling requirements would thus dictate worldwide labeling, at a huge cost, to the confusion (if not outright deception) of consumers outside the state. The existence of more effective and less burdensome alternatives was the subject of extensive trial testimony and evidence.

*24 Marketing and other experts addressed Vermont's purported labeling requirements as compared to an information campaign based upon point of sale placards aimed at the consumer market, direct mailings and invoice information aimed at the commercial and industrial markets, and the other informational tools that NEMA had offered to provide, (See pp. 13-14 above). Witnesses at trial included a member of the Marketing Department of a major university, whose Ph.D thesis subject was the psychology of shopping behavior related to packaging and point of sale materials. (JA97-98).

This expert analyzed at length the efficacy of point of sale placards and the other mechanisms NEMA had offered as compared to the labeling requirements the State seeks to impose. (JA 96-118, 396-430). Based upon its review of his testimony and all the other evidence, the District Court made the factual finding that the State's labeling scheme would be wholly ineffective: "[T]he symbol 'Hg,' together with *25 any explanatory note on the packaging, will be ignored on already cluttered bulb packaging at the time of purchase. In addition, at the end of a lamp's useful life, the symbol 'Hg' without packaging that was thrown away years before, will be rendered irrelevant." 72 F. Supp.2d at 453.

This conclusion was supported by substantial evidence. With respect to the consumer market, which accounts for only 15 percent of mercury-containing lamp usage (JA257), on-product or on-package warnings are largely ineffective, in substantial part due to the small size of the warnings depictable on a package or product. The inherent space limitations of this means of communication severely handicaps these warnings in their ability to compete with the many other extant stimuli for the very limited span of a human attention. Consumer perception of packaging has thus been termed "highly selective" and, indeed, is primarily pictorial, rather than verbal, further decreasing the effectiveness of information panels like those Vermont *26 is demanding. (JA410-12, 415, Supplemental JA633-37, JA99-100, 104-05.

These problems would be exacerbated in the case of the "Hg" in a circle because, as the district court found, "[a]bsent an extensive education campaign, the symbol 'Hg' will be meaningless." 72 F. Supp.2d at 453. Indeed, when cross-examined, the State's own marketing expert, Dr. Kieff, sought to disavow any endorsement of the "Hg" symbol as effective. (JA 457-58).

By contrast, signs at the point of purchase, which lamp manufacturers have proposed as an alternative to product and package labeling, do not suffer from the inherent space constraints of onpackage or on-product labeling. Because of their potentially much greater size, they are better able to compete for human attention. Researchers have found point of purchase advertising to be an effective mechanism for influencing consumer behavior, as a *27 result of which manufacturers spend over \$12.7 billion per year on point of purchase advertising. (JA100-02).

In fact, point of purchase advertisements have been found to be the most powerful means for altering shopper behavior among price-reduction, newspaper advertising, and point of purchase display. (JA101). For example, studies have found that the likelihood that a consumer will purchase light bulbs is nearly three or more times greater if point of purchase signs are used to promote the bulbs. (JA101). Thus, while on-the-product and on-the-package labels are not effective, point of purchase methods are. (JA99, 101, 105-07) ("[C]ommunication of the Vermont messages would be effective via Point of Purchase signage. In contrast, the use of information panels on packaging and/or the product, on the basis of evidence available, is not a viable route.")

The district court found this evidence highly persuasive, and found that the State had failed to present evidence of its own that would lead to a *28 contrary conclusion: the State has "not persuasively explained why the manufacturers' offer to provide point-of-sale informational signs in retail stores which inform about proper disposal of mercury-containing lamps would not, standing alone, be equally as effective." 72 F. Supp.2d at 455.

Indeed, in other circumstances where Vermont had wanted to convey information to consumers about the characteristics of consumer products, it had explicitly provided manufacturers the option of either labeling the product itself or posting point of sale placards as NEMA proposed here. It had done so because "[t]he shelf labeling option drastically reduces, if not eliminates entirely, any economic burdens placed by Veirmont's regulation on interstate commerce." (JA119-20, 136).

Even the State of California, which has over 50 times the population of Vermont, allows manufacturers to use point of purchase methods to convey to consumers information required by the State concerning the far *29 more immediate matters of known carcinogens or reproductive toxicants in consumer products. Specifically, the implementing regulations for California's consumer-information initiative (Proposition 65) permit manufacturers to provide state-required information regarding the presence of carcinogens or reproductive toxins in consumer products by means of "shelf-labeling, signs ... or a combination thereof." See Cal Code Regs. tit. 22 § 12601(b)(1)(B) (JA121, 137). These kinds of warnings are deemed "clear and reasonable" as a matter of law. Id.

Amicus State of New York (on behalf of itself and other States) blatantly misleads the Court in suggesting that Connecticut and Minnesota have also passed laws requiring the labeling of mercury-containing lamps. Am.Br. at 3 & n.l. Connecticut does not require the labeling of any mercury-containing lamp but rather provides manufacturers the option of either product/package labeling or providing "printed material ... to retailers," Conn. Pub. Act 99-228 § 2(a), a *30 non-labeling option. The amicus brief includes in its Addendum A-I only the part of § 2(a) that describes product/package labeling, cutting the statute mid-sentence to excise the part of § 2(a) quoted above that provides the non-labeling option. The full text of the Connecticut law is included in Addendum A to this brief. Similarly, Minnesota law absolutely does not retire the labeling of mercury-containing lamps, as the Minnesota Waste Management Act § 116.92(3) plainly shows, enumerating specifically the products that are required to be labeled and not including lamps among them. See Amicus Br., Addendum A-2, [FN4]

FN4. Amicus State of New York further misleads the Court by holding out a 1999 bill from the State of Maine, which was amended since the version included in the amicus brief. Am.Br. at 3 & n.l, and Addendum A-5. In fact, the only proposed legislation currently before the Maine legislature specifically excludes mercury-containing lamps from any product or packaging labeling requirement (S.B. 734 § 1662(1)) and instead provides that "invoice" information (or another "separate document") should be used to provide the statutorily-required information with respect to lamps, S.B. 734 § 1662(2)). See Addendum B to this Brief. Similarly, the bill from New Hampshire included as Addendum

A-4 in the amicus brief was amended after the version provided, so that all product/package labeling was eliminated. See Addendum C to this Brief.

*31 The trial evidence firmly established that product and package labeling were not effective ways of addressing the consumer market. Nor would Vermont's labeling requirements be an effective way to reach commercial or public sector buyers, who account for 85% of mercury-containing lamp usage. (JA257). Trial testimony established that the key to a successful strategy for this sector would be to provide information regarding the State's lamp disposal requirements to the relevant decisionmaker - the person whose job it is to set or oversee the company's practices regarding facility cleaning and trash removal, including lamp disposal. (JA107-09). The State's marketing expert, Dr. Kieff, conceded that this would be "absolutely essential" to changing disposal behavior in the commercial setting. (JA463).

But the Vermont statute does not succeed in conveying information to these individuals. In most commercial settings, and certainly in any large ones, the decisionmaker is likely to be a building manager, *32 and that person is highly unlikely to view the product or package labeling Vermont would require. (JA107-09, 421-24). The State's expert, Dr. Kieff, conceded as much. (JA465-66). Rather, the decisionmaker can be reached effectively by providing him or her printed information sheets or invoice notices setting forth Vermont's unique lamp disposal requirements. This is precisely what NEMA proposes to do. (JA 107-09, 421-24).

STANDARD OF REVIEW

A district court decision granting a motion for preliminary injunction is reversible only for abuse of discretion. <u>McNeilab, Inc. v. American Home Products Corp.</u>, 848 F.2d 34, 37 (2d Cir. 1988). The decision here was founded upon factual findings based upon extensive evidence presented through live witnesses. Those findings may be set aside only if clearly erroneous. *Id.* The district court's evidentiary rulings rise to reversible error only if they are an *33 abuse of discretion. <u>United States v. Williams</u>, 205 F.3d 23, 33 (2d Cir. 2000).

SUMMARY OF ARGUMENT

The District Court did not abuse its discretion in concluding that NEMA is likely to succeed on the merits of its Commerce Clause and First Amendment claims. Because the State is shielded by the Eleventh Amendment from having to answer for its unconstitutional conduct in damages, and because First Amendment rights are at stake, the District Court did not abuse its discretion in concluding that the harms that the Vermont labeling requirements will inflict are irreparable. The District Court's order granting NEMA.'s motion for a preliminary injunction should be affirmed.

ARGUMENT

Preliminary injunctive relief is appropriate when the moving party shows irreparable harm and a likelihood of success on the merits. *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 70 (2d Cir. 1996) (" *IDFA*"). The District Court did not abuse its *34 discretion in concluding that NEMA's Commerce Clause and First Amendment claims satisfy both these requirements. [FN5]

FN5. The District Court did not deem it necessary to consider NEMA's federal preemption or substantive due process claims, 72 F. Supp.2d at 450 n.l, which provide additional grounds for the injunctive relief NEMA sought.

I. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN CONCLUDING THAT NEMA MEMBERS WILL SUFFER IRREPARABLE INJURY IN THE ABSENCE OF AN INJUNCTION.

The District Court properly concluded that the Vermont labeling requirements would cause NEMA members irreparable injury in two distinct ways. 72 F. Supp.2d at 454. First, the labeling requirements would cause lamp manufacturers to incur millions of dollars in compliance costs. But the State could not be required to pay damages to compensate for these costs due to the bar established by the Eleventh Amendment. Second, the labeling requirements violate the First Amendment, and First Amendment violations constitute *per se* irreparable injury.

*35 A. The State of Vermont's Labeling Requirements Inflict Irreparable Harm Because the State Cannot Be Required to Pay Damages.

The District Court found that the costs imposed by the labeling requirements would be "great" and "substantial." 72 F. Supp.2d at 453-54. The State has not begun to show that these findings were clearly erroneous, as it concedes it must do to see them overturned. Vt.Br. 9-10. Indeed, the evidence before the District Court demonstrated that lamp manufacturers would have to expend millions of dollars to come into compliance with the Vermont labeling requirements (even assuming that such compliance were possible). (See pp. 18-20 above). The State may quibble about the precise costs of compliance, e.g., Vt.Br. 11-14, but it cannot seriously deny that they are substantial.

The Eleventh Amendment, however, would preclude lamp manufacturers from recovering monetary damages for these millions of dollars of compliance costs. See *36 Edelman v. Jordan, 415 U.S. 651, 663 (1974). [FN6] Irreparable harm is thus established in this case, because the State of Vermont's lamp and package labeling requirements would inflict monetary harm on manufacturers for which the State could not be required to answer in damages. See United States v. New York, 703 F.2d 92, 93 (2d Cir. 1983) ("Beechcraft would suffer irreparable business damages [absent a preliminary injunction] because the Eleventh Amendment precludes Beechcraft from suing New York in federal court for any damages Beechcraft suffers."); Blum v. Schlegel, 830 F. Supp. 712, 725 (W.D.N.Y. 1993) ("[T]he Second Circuit has determined that in cases where the defendant is protected by the Eleventh Amendment which thus renders the plaintiff unable to recover monetary damages, the injury will be irreparable.") (citing United States v. New York), aff'd, *37 18 F.3d 1005 (2d Cir. 1994); New York State Trawlers Ass'n v. Jorling, 764 F. Supp. 24, 26 (E.D.N.Y.) ("[T]he Court of Appeals has recognized that, where such damages cannot be later collected because the defendant enjoys eleventh amendment immunity, the damages become irreparable.") (citing United States v. New York), aff'd 940 F.2d 649 (2d Cir. 1991).

FN6. The Eleventh Amendment does not, however, bar plaintiffs from obtaining the declaratory and injunctive relief sought in this lawsuit. <u>Edelman v. Jordan</u>, 415 U.S. at 664; <u>Will v. Michigan Dep't of State Police</u>, 491 U.S. 58, 71 n.10 (1989).

Notwithstanding this direct precedent, Vermont remarkably contends that "this Court ... [has] rejected the notion that irreparable harm results from sovereign immunity's bar on a plaintiff's ability to recover any funds expended in complying with a challenged law." Vt.Br. 18. The authority cited for this contention is this Court's decision in *United States v. New York*, which as quoted above establishes precisely the opposite principle. Indeed, the State concedes that this Court in *State of New York* "affirmed the grant of a preliminary injunction on the grounds that the Eleventh Amendment precluded the recovery of damages from the State of New York." Vt.Br. 22. Unmoved by *38 this concession, this State further contends that this Court "summarily affirmed District Judge Miner's finding" in *State of New York* that one of the plaintiffs - Beechcraft, Inc. - was losing customers and that this "peculiar" harm, not the Eleventh Amendment bar, was the basis for this Court's finding of irreparable harm. Vt.Br. 22. Noticeably absent from this characterization is any citation to this Court's opinion in *United States v. New York. Id.* In fact, as quoted in the text above, and as relied upon subsequently by other district courts, this Court based its conclusion of irreparable harm in *United States v. New York* solely on the Eleventh Amendment bar. *See* 708 F.2d at 92, 93.

Indeed, the principle of State of New York and the other above cited cases - that monetary harm becomes an irreparable harm where it is not compensable because of the Eleventh Amendment - is but one instance of a unifying principle of irreparable harm-analysis identified by this Court in *39

Brenntag Int'l. Chem. v. Bank of India, 175 F.3d 245 (2d Cir. 1999). The Brenntag Court observed that "irreparable harm" will be found "where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." 175 F.3d at 249-50. The Court held pursuant to this unifying principle that monetary harm becomes irreparable harm where the party seeking a preliminary injunction would not be able to recover monetary damages because the opposing party is insolvent. Id. (collecting authorities).

In both the Eleventh Amendment context, see <u>United States v. New York</u>, 708 F.2d at 93-94, and in the insolvency context, see <u>Brenntag</u>, 175 F.3d at 249-50, this Court has found it sufficient for irreparable harm purposes that the party seeking the preliminary injunction would not be able to be returned to the position it previously occupied because it could not recover its monetary damages were it to prevail on the *40 merits. This requirement is easily satisfied here, because given the barrier to any monetary awards against the State, NEMA members obviously could not be returned to the position they previously occupied once they had incurred the millions of dollars necessary to retool their worldwide facilities. This Court has never suggested, as Vermont does here (see Vermont Br. 12, 22), that if damages are unavailable because of immunity, a company seeking a preliminary injunction must also show, in addition to the Eleventh Amendment bar, some specified, "peculiar" injury if the injunction is denied. [FN7]

FN7. In the absence of any support for this proposition in the decisions of this Court, Vermont cites cases from elsewhere, only two of which even involved the Eleventh Amendment. See Vt.Br. 23. Those cases observed that "the Eleventh Amendment bar simply indicates irreparability, but does not, in itself, establish harm." <u>Kansas Health Care Ass'n, Inc. v. Kansas Dept. of Soc. and Rehabilitation Servs.</u>, 31 F.3d 1536, 1543 (10th Cir. 1994); IDEA v. <u>Amestoy</u>, 898 F. Supp. 246 (D. Vt. 1995) (quoting Kansas Health for this proposition), rev'd on other grounds, 92 F.3d 67 (2d Cir. 1996). This non-controversial proposition is of no avail to Vermont, whose labeling requirements would, as the District Court found, harm manufacturers by imposing substantial compliance costs. In Kansas Health, the Tenth Circuit set forth a definition of "harm" that easily encompasses the compliance costs that would be imposed on the lamp manufacturers here: "harm [is] a legally cognizable injury." 31 F.3d at 1543.

*41 The State also claims that the harm to manufacturers is not irreparable because compliance costs might be passed on to consumers. Vt.Br. 10-11. But the District Court merely speculated this might "possibly" occur. 72 F. Supp.2d at 453. In any event, other Courts of Appeals have recognized the "economic truth" that passing on costs, i.e., increasing prices, will cause a reduction in product demand and therefore itself cause injury to the manufacturer. See Adams v. Watson, 10 F.3d 915, 923 (1st Cir. 1993) (it is an economic fact that an increase in raw milk prices "pass[ed] along" to consumers will decrease demand and cause injury); Competitive Enter. Inst. v. National Hwy. Traffic Safety Admin., 901 F.2d 107, 125 (D.C. Cir. 1990) (same); Alcan Sales Div. of Alcan Aluminum Corp. v. United States, 693 F.2d 1089, 1092 (Fed. Cir. 1982) (import surcharge would cause injury because if importers "pass the cost of the surcharge through to *42 consumers," demand will decrease). [FN8] Because NEMA members would be unable to recover monetary damages for these injuries either, their losses would be irreparable.

FN8. The <u>State cites Wisconsin Gas Co. v. FERC</u>, 758 F.2d 669, 674 (D.C. Cir. 1985), for the proposition that "[t]he ability to recoup compliance costs through product pricing is ... no different than the ability to seek redress through money damages." Vt.Br. at 10, 21. However, this inference cannot properly be drawn from *Wisconsin Gas* in light of the D.C. Circuit's conclusion why irreparable harm could not be found there: "[T]he allegations made by petitioners are so speculative and hypothetical that it would be difficult to conclude that irreparable injury would occur even if the allegations were supported by evidence. The fact that petitioners have not attempted to provide any substantiation is a clear abuse of this court's time and resources." 758 F.2d at 675.

In short, the State has identified no authority for holding lamp manufacturers to a standard of irreparable harm that requires them to show more than that they could not recover their monetary damages from the State under the Eleventh Amendment. [FN9] As the *43 District Court concluded, the manufacturers have made that showing and thus fully carried their burden.

FN9. The State argues that this rule would make preliminary injunctive relief more readily available against governmental defendants than private defendants. Vt.Br. 15. But this overlooks the fact that this Court requires a showing of probability of success on the merits to obtain preliminary injunctive relief against a governmental defendant, while a plaintiff suing a private party need only show sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in the movant's favor. *IDFA v. Amestoy*, 92 F.3d at 70.

B. The Denial of First Amendment Rights by the State's Labeling Requirements Constitutes Irreparable Harm.

The State of Vermont nowhere disputes the well-established rule that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." <u>IDFA v. Amestoy</u>, 92 F.3d at 71 (quoting <u>Elrod v. Burns</u>, 427 U.S. 347, 373 (1976)). Instead, under the heading of irreparable harm, the State of Vermont argues only the merits of the manufacturers' First Amendment claims. Vt.Br. 23-24. But irreparable injury is "separate and distinct" from the merits of the plaintiff's claim. <u>Church of Scientology Int'1 v. Elmira Mission of the Church of Scientology</u>, 794 F.2d 38, 44 (2d Cir. 1986).

*44 Of course, NEMA submits that it has established the merits of its First Amendment claim, (see pp. 70-74 below). But the issue being addressed here is irreparable injury, and that requirement is necessarily satisfied when a First Amendment violation is asserted.

Consequently, the District Court properly concluded that the harm that Vermont's requirements would inflict if an injunction were not issued would be irreparable.

II. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN CONCLUDING THAT PLAINTIFF IS LIKELY TO SUCCEED ON THE MERITS.

The District Court did not abuse its discretion in concluding that NEMA is likely to succeed on the merits of each of its Commerce Clause and First Amendment claims.

*45 A. The State of Vermont Is Violating the Commerce Clause by Projecting Vermont Legislation All Over the World, by Interfering with the Ability of Other States to Regulate Within Their Borders, and by Unduly Burdening Interstate Commerce.

The Commerce Clause provides that "[t]he Congress shall have power ... [t]o regulate commerce ... among the several States." <u>U.S. CONST, art. I, § 8, cl. 3</u>. "It is long-established that, while a literal reading evinces a grant of power to Congress, the Commerce Clause" also directly limits the powers of the states. <u>Wyoming v. Oklahoma</u>, 502 U.S. 437, 454 (1992) (citing authorities).

A statute can run afoul of the Commerce Clause in several ways. First, a statute can have the practical effect of regulating commerce occurring beyond the state's borders. <u>Healy v. The Beer Inst.</u>, <u>491 U.S. 324, 336 (1989)</u>. Such a statute is per se unconstitutional, without any consideration of the statute's putative local benefits or the legislature's intent to regulate interstate commerce. See id.

*46 Second, a statute can interfere with the legitimate regulatory schemes of other states, and in this regard the Court must consider "what effect would arise if not one, but many or every, State adopted similar legislation." *Id.*

Third, even if a statute "has only indirect effects on interstate commerce and regulates evenhandedly," a court must "examine[] whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." <u>Brown-Forman Distillers Corp. v. New York State Liquor Auth.</u>, 476 U.S. 573, 579 (1986); see also Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). To apply this test, the court must balance the burden imposed on interstate commerce against the local benefit, and must consider whether the local interest could be served as well with a lesser impact on interstate activities. <u>Great Atl. & Pac. Tea Co. v. Cottrell</u>, 424 U.S. 366, 372 (1976); Pike, 397 U.S. at 142.

The District Court did not abuse its discretion in concluding that the Vermont labeling requirements would violate each of these Commerce Clause prohibitions. First, the District Court found, and Vermont never disputes, that "the labeling scheme ... essentially requires lamp manufacturers to label all lamps in conformity with Vermont law" and therefore "Vermont is presuming to legislate outside its own boundaries." 72 F. Supp.2d at 455; see also id at 452. Second, the District Court found that "[b] ecause of spatial limitations, any other State which may want to control the disposal of mercury-containing lamps by insisting on a different message would either have to abandon a labeling proposal or choose to be bound by Vermont's legislated message." Id. at 455; see also id. at 452 (finding that Vermont's labeling when it appears in "jurisdictions other than Vermont will cause confusion")). Third, the District Court found Vermont's "onerous labeling requirements" would impose a "great cost" on manufacturers - a cost that is *48 "clearly excessive in relation to the asserted local benefits." Id. at 454-55.

Each of these constitutional defects provides an independent reason why the Vermont labeling requirements are unconstitutional. The State, however, attempts to answer only the third of these points, makes only brief mention of the second and ignores the first.

1. The Vermont Requirement Unconstitutionally Regulates Commerce Outside Vermont.

The District Court found that "[a]s a practical matter, it appears lamp manufacturers ... will have to label all bulbs manufactured world-wide with the Vermont-required label." 72 F. Supp.2d at 452; id. at 455. The State of Vermont never disputes this finding. Indeed, the State in other contexts explicitly relies upon it. Vt.Br. 34.

However, the Commerce Clause absolutely bars any State from imposing a regulation "the practical effect of [which] is to control conduct beyond the *49 boundaries of the State." Healy v. The Beer Inst., 491 U.S. 324, 336 (1989) (citing Brown-Forman Distillers Coarp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986). Just as "New York has no power to project its legislation into Vermont," Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 521 (1935) (Cardozo, J.), Vermont has no power to project its legislation into New York or other states. See Cotto Waxo Co. v. Williams, 46 F.3d 790, 793 (8th Cir. 1995) ("[U]nder the Commerce Clause, a state regulation is per se invalid when it has an extraterritorial reach, that is, when the statue has the practical effect of controlling conduct beyond the boundaries of the state.") (emphasis added) (citations omitted); Southern Pac. Co. v. Arizona, 325 U.S. 761, 775 (1945) (striking down State law limiting length of trains within State's borders, because "[t]he practical effect of [a law limiting train lengths] is to control train operations beyond the boundaries of the state exacting it because of the necessity of *50 breaking up and reassembling long trains ... before entering and after leaving the regulating state.").

The Commerce Clause prohibits extraterritorial legislation per se, "regardless of whether the statute's extraterritorial reach was intended by the legislature." *Healy*, 491 U.S. at 336. This rule was applied, for example, to strike down a Nevada statue requiring the NCAA to provide specified procedural guaranties during enforcement actions involving rules infractions. *NCAA v. Miller*, 10 F.3d 633 (9th Cir. 1993). Given the NCAA's own need to utilize uniform enforcement procedures, "it would have to apply Nevada's procedures to enforcement proceedings throughout the country." 10 F.3d at 639. This would "run[] afoul of the Commerce Clause [because] a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." *Id.* (citation *51 omitted); *see also American Libraries Ass'n v. Pataki*, 969 F. Supp. 160,

174 (S.D.N.Y. 1997) (striking down a New York prohibition against indecent communications via the Internet to New York minor residents because only by following New York's law everywhere could someone outside New York be sure not to violate New York requirements).

The State of Vermont has trampled this fundamental Commerce Clause principle by demanding that lamp manufacturers label lamps and their packaging, knowing that this requirement would have to be carried out in the rest of the country (and the world) as well.

2. The State is Unconstitutionally Interfering With the Abilities of Other States to Regulate Within Their Borders.

A second, independently-dispositive reason identified by the District Court why the Vermont labeling requirement violates the Commerce Clause is that the Clause "protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another." *52 72 F. Supp.2d at 455 (quoting Healy, 491 U.S. at 336-37). As the District Court recognized, under Healy, 491 U.S. at 336, this prohibition entails consideration of both "how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." 72 F. Supp.2d at 455 (quoting Healy).

The Vermont labeling requirements are an archetypal example of a law this Commerce Clause prohibition was intended to forbid. As described above, the District Court found that Vermont's labeling requirement would preclude other States from implementing labeling requirements of their own choosing due to the limited space on packaging and lamps available for labeling. *Id.* Different states could also easily subject lamp manufacturers to conflicting labeling requirements. *See, e.g., NCAA v. Miller, 10 F.3d at 639* (striking down as a per se Commerce Clause violation a Nevada statute imposing *53 procedural requirements for NCAA disciplinary proceedings, in part because Nevada "is not the only state that has enacted or *could enact* legislation that establishes procedural rules for NCAA enforcement proceedings [which] could easily subject the NCAA to conflicting requirements") (emphasis added). [FN10]

FN10. The modern case law of the Supreme Court (e.g., Healy) and other Circuits (e.g., NCAA) shows that it is fanciful for the State to argue that the District Court made a "clear legal error" when it considered how Vermont's law would interact with legislation that other States could enact. See Vt.Br. 37.

Furthermore, by setting forth Vermont's unique disposal requirements (see pp. 14-15 above), the Vermont-mandated labels would lead lamp users in other states either to assume that they are free from any disposal requirements (which is not true for all users anywhere) or that they too are subject to the same requirements as Vermont users (which is true only in Minnesota). See, e.g., NCAA v. Miller, 10 F.3d at 639. For this reason, the District Court made the factual finding that Vermont's labeling when it appears in *54 "jurisdictions other than Vermont will cause confusion... " 72 F. Supp.2d at 452.

Because the Vermont labeling requirement would interfere with the ability of other states to regulate within their own borders, the requirement violates the Commerce Clause.

3. The State Is Unconstitutionally Burdening Interstate Commerce.

The District Court identified yet a third reason why the Vermont requirements are unconstitutional under the Commerce Clause. As explained above, the Commerce Clause bars any state from enacting a law that imposes a burden on interstate commerce that is "clearly excessive in relation to the putative local benefits." 72 F. Supp.2d at 455 (quoting *Pike*, 397 U.S. at 142); *Brown-Forman Distillers*, 476 U.S. at 579. This test requires the court to balance the burden the law imposes on interstate commerce against any local benefit, and to consider whether any local interest could be served as well with a lesser impact on interstate activities. *55 Great Atl. & Pac. Tea Co. v. Cottrell,

424 U.S. at 366; Pike, 397 U.S. at 142.

The District Court found it unnecessary to adopt any specific cost estimate "in order to find that the cost of alterations to a manufacturer's production line would be substantial [and] would require manufacturers either to stop selling in Vermont, to change its distribution system to isolate bulbs going to Vermont, or to label all lamps to comply with Vermont law."FN[FN11] 72 F. Supp.2d at 453-54. Moreover, the District Court found that Vermont's required labeling would be "ignored" and "irrelevant," id. at 453, and that "even if the law were to operate as envisioned, it only addresses ... a very small portion of the *56 problem of mercury entering the environment." Id. at 454.

FN11. Contrary to Vermont's assertion (Vt. Br. 34), the District Court did not make a finding that the appropriate cost figures to use in evaluating Vermont's labeling requirements against the constitutional standards were the costs of "creating separate production lines for products sold in Vermont." Rather, the District Court described the "evidence" that NEMA presented, 72 F. Supp.2d at 453, and made qualitative findings about costs - that they would be "great," "substantial," and (as quoted above) would halt sales to Vermont, require a new distribution system, or require worldwide labeling. *Id.* at 453-54.

The Court further found that the State has "not persuasively explained why the manufacturers' offer to provide point-of-sale informational signs in retail stores which inform about proper disposal of mercury-containing lamps would not, standing alone, be equally as effective." *Id.* at 455. The District Court thus concluded that the Vermont requirement's "burdens are clearly excessive in relation to the asserted local benefits." *Id.*

The case for invalidation of Vermont's requirements was even stronger than that presented in <u>Bibb v. Navajo Freight Lines, Inc.</u>, 359 U.S. 520 (1959). There the Supreme Court struck down an Illinois statute requiring the use of a certain type of rear-fender mudguard on trucks and trailers required by no other state. The cost of installing the Illinois mud flaps was \$30.00 or more per vehicle, and the district court determined that the Illinois mud flap *57 had no advantages over the conventional mud flap used elsewhere.

The Court acknowledged that state "safety measures carry a strong presumption of validity when challenged in court." 359 U.S. at 524. However, because the Illinois flap was "out of line with the requirements of the other States," because compliance was burdensome and (somewhat) expensive, and because the state's showing of special need was not "compelling," the Supreme Court struck down the Illinois mud flap requirement as violative of the Commerce Clause. 359 U.S. at 529-30.

Similarly, in *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429 (1978), the Supreme Court struck down a Wisconsin regulation barring the operation of 65-foot double trailers on state highways. Substantial evidence indicated that 65-foot double trailers were as safe as the 55-foot single trailers that Wisconsin did allow. Moreover, although the Court did not deem it necessary to determine with specificity the industry- *58 wide costs that would be incurred, it noted the testimony that one company would face costs in excesses of \$2 million annually to make the adjustment in operations required by the Wisconsin law. *Id.* at 439 n.14.

Although the 55-foot singles that were legal in Wisconsin were not actually prohibited in any other state, the *Raymond* Court found the absence of legal inconsistency irrelevant. 434 U.S. at 446 n.23. The Court instead held that the "challenged regulations violate the Commerce Clause because they place a substantial burden on interstate commerce and they cannot be said to make more than the most speculative contribution to highway safety." *Id.* at 447; see also *Dixie Dairy Co. v. City of Chicago*, 538 F.2d 1303, 1308-11 (7th Cir. 1976) (striking down as unduly burdensome Chicago statute requiring that all out-of-state dairies and dairy farmer suppliers be subjected to city-operated inspections, when the dairies and *59 farmers were already subject to comparable inspections by the states in which they were located).

Like Illinois in Bibb and Wisconsin in *Raymond Transportation*, Vermont has enacted unique requirements applicable to a good or service sold in interstate commerce. These requirements are "out of line" with the rest of the country (and the world). <u>Bibb</u>, <u>359 U.S. at 529-30</u>. The burdens imposed on interstate commerce by the requirements are "great" and the benefits to Vermont are "very small." 72 F. Supp.2d at 453-55. Alternative ways are available for Vermont to achieve its objectives while "doing away with its onerous labeling requirements." 72 F. Supp.2d at 455.

Accordingly, the Vermont requirements violate the Commerce Clause. *Id.*; <u>Raymond</u>, 434 U.S. at 447; <u>Dixie Dairy</u>, 538 F.2d at 1310-11.

Faced with the District Court's adverse findings of fact, and the rule that such findings may be reversed only if "clearly erroneous", Vermont must contend that only its legislature can balance the *60 benefits of the labeling requirement against the burdens it imposes and the alternatives that NEMA has proffered. (Vt.Br. 29-32). Such a rule would eviscerate *Pike*, which explicitly indicated that it is "the Court [that] has candidly undertaken a balancing approach in resolving these issues." 397 U.S. at 142 (emphasis added). See also, e.g., Cotto Waxo Co., 46 F.3d at 794 ("This [Pike] balancing test requires us to consider the Act's burdens on interstate commerce, the Act's local benefits, and the balance between the two.") (emphasis added).

Indeed, this Court has not merely endorsed, but mandated, precisely the weighing of costs, benefits and alternatives that was engaged in by the District Court here. In *Association of Int'l Automobile Mfrs., Inc. v. Abrams,* 84 F.3d 602 (2d Cir. 1996), this Court reversed and remanded a lower court decision dismissing a Commerce Clause challenge to a state statute requiring manufacturer testing of, and labeling regarding, the ability of new car bumpers to avoid *61 collision damage. "Since there are genuine factual issues as to both the claimed burdens and the putative benefits created by the New York bumper statute, we remand for further development of the record in order to permit the district court to apply the *Pike v. Bruce Church* balancing test." 84 F.3d at 613. Far from deferring to the views of the legislature, as Vermont suggests, this Court termed the "legislative assumptions" about the statute's benefits "debatable", citing among other evidence affidavits from the plaintiff trade association's members. *Id.* at 612-13. This is precisely the kind of evidence examined here by the lower court. *Accord*, e.g., *Cotto Waxo Co.*, 46 F,3d at 794-95 (noting the strengths and weaknesses of the evidence that had been presented by affidavit and legislative history on both public benefit and burden on commerce, and holding that "[t]he constitutionality of the Act should be tested at trial.").[FN12]

FN12. Vermont relies heavily upon <u>Minnesota v. Clover Leaf Creamery Co.</u>, 449 U.S. 456, 470 (1981), but that Court's statement about not substituting its evaluation of legislative facts for those of the legislature was in the section of the opinion addressing an Equal Protection Challenge, and dealt only with the purposes served by the statute. When it came to the Commerce Clause, the Supreme Court made its own and detailed determinations regarding both the burdens imposed by the statute, 449 U.S. at 472-73, and the efficacy of the specific alternatives that had been suggested by the plaintiffs, *id.* at 473-74. The Court upheld the law only after making its own finding that the burdens were small and the alternatives ineffectual (*id.*), the exact opposite of the findings made by the District Court here.

*62 The District Court properly applied Pike to strike down the State's labeling requirements.

4. An Absence of Discrimination Does Not Remove the Statute from the Purview of the Commerce Clause.

Vermont argues that its statute does not discriminate against interstate commerce and therefore "does not implicate the concerns addressed by the Commerce Clause." (Vt.Br. 29; see also id. at 39 ("[I]ost profits resulting from compliance with a non-discriminatory statute are not a Commerce Clause issue.")) But as to the first two ways in which the Vermont labeling requirements violate the Commerce Clause - their extraterritorial effects, and interference with the ability of other states to

*63 regulate within their borders - the issue is not one of discrimination, but of conduct that exceeds the inherent limits of a state's powers.

As to the third Commerce Clause issue - the burdens imposed by the State's requirements as compared to the benefits achieved - Vermont's argument that nondiscrimination is dispositive cannot be reconciled with Supreme Court precedent. Indeed, Supreme Court doctrine on this precise point could not be more clear:

[O]ur case law yields two lines of analysis: first, whether the ordinance discriminates against interstate commerce, and second, whether the ordinance imposes a burden on interstate commerce that is clearly excessive in relation to the putative local benefits.

C & A Carbone, Inc. v. Town of Claristown, N. Y., 511 U.S. 383, 390 (1994) (citations omitted). Indeed, any other approach would read the Pike test out of existence; that decision squarely held that even if a statute "has only indirect effects on interstate *64 commerce and regulates evenhandedly," a court must "examine[] whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." Browm-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. at 579. Elsewhere in its own brief, the State concedes this, see Vt.Br. 27-28.

This Court's precedents also belie the notion that an absence of discrimination is dispositive. As noted above, Association of Int'l Automobile Mfrs., Inc. v. Abrams involved a Commerce Clause challenge to a state statute requiring manufacturer testing of, and labeling regarding, the ability of new car bumpers to avoid collision damage. Although the statute applied equally to all cars wherever manufactured and provided no advantage to those made in New York, this Court held that the district court was required under Pike to balance the costs and benefits and determine if the latter could be promoted as well with a lesser impact on interstate commerce, 84 F.3d at 612-13. Decisions *65 by other courts of appeals are to the same effect. See, e.g., Blue Circle Cement Inc. v. Board of County Comm'rs, 27 F.3d 1499,1511 (10th Cir. 1994) ("The [district] court's exclusive focus on animus against interstate interests neglected completely the role of the dormant Commerce Clause in prohibiting unreasonable incidental burdens on interstate commerce, even when there is no discriminatory animus involved against interstate commerce"); Environmental Technology Council v. Sierra Club, 98 F.3d 774, 785 (4th Cir. 1996) ("The second tier [of Commerce Clause analysis] applies if a statute regulates evenhandedly and only indirectly affects interstate commerce"); Cotto Waxo Co. v. Williams, 46 F.3d 790 (8th Cir. 1995) (although statute did not discriminate against interstate commerce, question whether it failed the Pike test is remanded for trial).

5. The Challenged Conduct Has Not Been Immunized from Commerce Clause Scrutiny.

The State contends for the first time on appeal that the federal government has by statute authorized ***66** it to impose the lamp labeling requirements even if otherwise violative of the Commerce Clause. But this Court will not consider arguments presented for the first time on appeal. *E.g.*, *Johnson v. The Smithsonian Inst.*, 189 F.3d 180, 186n.3 (2d Cir. 1999) ("Because this argument is presented for the first time on appeal, we decline to consider it"); *SEC v. Monarch Funding Corp.*, 192 F. 3d 295, 308-09 (2d Cir. 1999) ("The general rule is that a federal appellate court does not consider an issue not passed upon below")(citation omitted). The State did not argue below that its labeling requirements were immune from Coitnmerce Clause attack due to specific federal authorization, and may not do so for the first time now.^[FN13]

FN13. The State only referenced the federal statute upon which it now relies in responding to NEMA's Supremacy Clause claim, not in defending against the Commerce Clause claim.

In any event, no federal statute authorizes Vermont to impose labeling requirements otherwise *67 barred by the Commerce Clause. While Congress may exempt state conduct from Commerce Clause scrutiny it "must manifest its unambiguous intent before a federal statute will be [so] read." Wyoming

<u>v. Oklahoma</u>, 502 U.S. 437, 458 (1992). "When Congress has not expressly stated its intent and policy to sustain state legislation from attack under the Commerce Clause, we have no authority to rewrite its legislation based on mere speculation as to what Congress probably had in mind." <u>New England Power Co. v. New Hampshire</u>, 455 U.S. 331, 343 (1982) (citations omitted). <u>New York v. United States</u>, 505 U.S. 144, 171 (1992), provides a classic example of a statute that did reflect the requisite "unambiguous intent," addressing a federal law that expressly granted states the authority to impose a surcharge on radioactive waste received from other states.

The federal Resource Conservation and Recovery Act (RCRA) relied upon by Vermont here merely provides that "[n]othing in [RCRA] shall be construed to *68 prohibit any State ... from imposing requirements ... which are more stringent than those imposed by [federal hazardous waste] regulations." 42 U.S.C. § 6929. That language simply confirms that RCRA was not intended to preempt all state hazardous waste law; it does not "unambiguously" and affirmatively authorize a state to impose requirements that would otherwise violate the Commerce Clause. [FN14]

FN14. Amicus New York argues that the federal Toxic Substances Control Act (TSCA) 15 U.S.C. § 2601, et. seq., also immunizes Vermont's labeling requirements from Commerce Clause attack. However, this argument is also untimely and meritless. It was not raised below, and the TSCA language cited merely states that "nothing in this chapter shall affect the authority of any State or political subdivision of a State to establish or continue in effect regulation of any chemical substance, mixture, or article containing a chemical substance or mixture." 15 U.S.C. 2617(a)(1) and (2) (emphasis added). This language, like that found in RCRA, only addresses the preemptive effect of the federal statute.

The Supreme Court has repeatedly interpreted similar federal statutes in just this fashion. For example, in *New England Power Co.*, the Court addressed a provision that a federal statute "shall not ... deprive a State ... its lawful authority now *69 exercised over the exportation of hydroelectric energy which is transmitted over a State Line." 455 U.S. at 332. The Court held that this language was intended "simply to define the extent of the federal legislation's pre-emptive effect on state law" and could not be read to "evince [] a congressional intent to alter the limits of state power otherwise imposed by the Commerce Clause." 455 U.S. at 341 (citations omitted). *Lewis v. BT Investment Managers, Inc.*, 447 U.S. 27, 49 (1980), similarly held that a savings clause was meant to preserve "state regulations ... even if they were more restrictive than federal law" but in no way affected "the boundaries marked by the Commerce Clause."

Indeed, the Fourth Circuit has held, in a case Vermont fails to bring to this Court's attention, that RCRA does "not contain any language indicating an unmistakably clear congressional intent to permit states to burden interstate commerce." *70 Environmental Technology Council v. South Carolina, 98 F. 3d 774, 783 (4th Cir. 1996). The Fourth Circuit reaffirmed its preliminary conclusion to that effect in a previous phase of the litigation, in which it had addressed arguments based upon the same RCRA provision Vermont purports to invoke here, see <u>Hazardous Waste Treatment Council v. South Carolina</u>, 945 F.2d 781, 783, 792 (4th Cir. 1991). [FN15]

FN15. Vermont relies upon *Old Bridge Chemicals, Inc. v. New Jersey Dep't of Envt'l Protection*, 965 F.2d 1287, 1296-97 (3d Cir. 1992), but consistent with the Supreme Court precedents cited above, that decision applied RCRA's savings clause to reject a preemption challenge, not a Commerce Clause challenge. Even that result has its limits; other decisions have held particular state programs preempted by RCRA notwithstanding its savings clause. *Blue Circle Cement, Inc. v. Board of Cty. Comm. of the County of Rogers*, 27 F.3d 1499, 1506-10 (10th Cir. 1994)(citing cases).

No federal statute has lifted the Commerce Clause limitations that the Vermont labeling requirements transgress.

B. The Labeling Requirements Violate the First Amendment.

The District Court correctly concluded that the Vermont labeling requirements violate the First Amendment, made applicable to the states through the *71 Fourteenth Amendment, <u>Wallace v. Jaffree</u>, 472 U.S. 38, 49 (1985).

The Vermont requirements compel commercial speech, in that they require manufacturers to add the State's prescribed language to their product and package labels. See <u>International Dairy Foods Ass'n v. Amestoy</u>, 92 F.3d at 71-73 ("TDFA") (compelled product or package labeling constitutes compelled commercial speech); <u>Memphis Publ'g Co. v. Leech</u>, 539 F. Supp. 405, 410-12 (W.D. Tenn. 1982) (applying commercial speech scrutiny to statute mandating that newspaper print legal warning in commercial advertisement).

As this Court held in IDFA, applying <u>Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of N.Y., 447 U.S. 557 (1980)</u>, a state labeling law that compels commercial speech must be struck down unless the law (1) concerns lawful activity and is not misleading; (2) promotes a substantial governmental interest, (3) directly serves the asserted state *72 Interest; and (4) is no more extensive than necessary to serve that interest. <u>IDFA</u>, 92 F.3d at 72.

The State of Vermont challenges the applicability of this four part test, but is forced to admit, albeit in a footnote (Vt.Br. 42 n.5), that this Court's decision in IDFA dictates its use. Indeed, the State is reduced to criticizing the IDFA decision (*id.*), but of course that authority is controlling unless reversed by en banc decision. *Lee v. Cammissioner of Internal Revenue*, 155 F.3d 584, 587 (2d Cir. 1998). [FN16]

FN16. Vermont incorrectly claims that "[t]he proper standard of review for statutes that compel commercial disclosures is the two-part 'reasonably-related' test in <u>Zauderer v. Office of Disciplinary Counsel</u>, 471 U.S. 626, 651 (1985)." (Vt.Br. 41.) This Court cited <u>Zauderer in IDFA</u> for the proposition that "disclosure requirements are permissible 'as long as [they] are reasonably related to the State's interest in preventing deception of consumers." 92 F.3d at 74 (quoting <u>Zauderer</u>). But the Court subjected the labeling requirement at issue in <u>IDFA</u>, which was not designed to prevent deception of consumers, to the general standard of review for commercial speech established by the Supreme Court in <u>Central Hudson</u>. It was therefore proper for the District Court here to subject the Vermont labeling requirements, which are also not designed to prevent deception of consumers, to the <u>Central Hudson</u> test.

*73 The District Court found that the Vermont labeling requirement fails two of the *Central Hudson/IDFA* requirements. First, as the District Court held, the Vermont requirement must "directly advance" the State's interest. 72 F. Supp.2d at 456. However, as described above, the District Court found that the Vermont labeling would be "ignored" and "irrelevant", *id.* at 453, and, in any event, would address only "a very small portion of the problem of mercury entering the environment." *Id.* at 454; see also id. at 456 ("By far, the largest source of mercury in the environment does not come from lamps.")). Vermont's requirements therefore "provide[] only ineffective or remote support for the government's purpose" and violate the First Amendment. *Central Hudson*, 447 U.S. at 564.

Second, the District Court concluded that Vermont's requirements "are far more extensive than is necessary" to serve its interest. 72 F. Supp.2d at 456. As described at pp. 13, 18-20 above, the District Court found that the Vermont requirements would compel *74 worldwide labeling of lamps, and that alternative means were available to achieve Vermont's goal. See <u>Memphis Publ'g</u>, 539 F. Supp. at 412 (striking down requirements that a required warning be printed in a space at least 30 percent the size of the entire advertisement, and in print no smaller than the largest type employed in the advertisement, because this was "more onerous than necessary to inform those sought to be informed.")

The District Court thus correctly concluded that "Vermont also has failed to meet its burden of justifying this labeling law under the First Amendment." [FN17] 72 F. Supp.2d at 456 (citing <u>IDFA</u>, 92 F.3d at 72)). [FN18]

FN17. The State contends that the District Court "erred in shifting the burden of proof onto Vermont." Vt.Br. 48. However, this Court held in *IDFA* that while the plaintiff seeking the preliminary injunction "must ... show a likelihood of success on the merits," the "State ... bears the burden of justifying its labeling law" under the First Amendment. *IDFA*, 92 F.3d at 72.

FN18. Vermont avers that several federal speech compulsions would also be unconstitutional under *Central Hudson* if the State's labeling requirements are unconstitutional. However, even without the benefit of any factual development as to the need for these particular statutes, the federal requirements are unlikely to be overbroad in that they are by definition intended and permitted to apply nationwide.

*75 C. Defendants Are Acting In Violation of 42 U.S.C. Section 1983.

This action is brought against defendants in their official capacities to prevent them from enforcing a state statute and rules promulgated thereunder that violate both the Commerce Clause, the First Amendment and the Fourteenth Amendment. <u>42 U.S.C. § 1983</u> provides a cause of action for violations of these constitutional provisions. *See Collins v. City of Harker Heights, Texas*, 503 U.S. <u>115</u>, 120 (1992) (First and Fourteenth Amendments); <u>Dennis v, Higgins</u>, 498 U.S. 439 (1991) (Commerce Clause). As such, NEMA is likely to prevail on the merits of its <u>Section 1983</u> claim as well.

III. THE DISTRICT COURT DID NOT ABUSE ITS DISCRETION IN ITS EVIDENTIARY RULINGS.

The State is far wide of the mark in its final, scattershot attempt to locate a reversible error in the District Court's evidentiary rulings. A trial court *76 has broad discretion over the conduct of a trial, and it's evidentiary rulings will lead to reversal only if they rise to the level of an abuse of discretion. The District Court's evidentiary rulings were well within the bounds of its wide discretion.

A. The Trial Court Did Not Err in Precluding the State From Relying Upon Affidavit Testimony By Witnesses Who Did Not Appear At Trial.

The State attempted to submit into evidence affidavit testimony from two witnesses who did not appear at trial, Lindberg and Atkinson. The District Court ruled: "I'm going ... to consider the affidavits that have been presented by both sides. However, when there appears to be contested issues of fact in those affidavits or in any of the issues that I have to resolve I will rely upon the live testimony." JA334.

The District Court's ruling was absolutely correct under this Court's decision in <u>Davis v. New York City Housing Authority</u>, 166 F.3d 432, 437-38 (2d Cir. 1999), holding that "[w]hile affidavits may be *77 considered on a preliminary injunction motion, motions for preliminary injunction should not be resolved on the basis of affidavits that evince disputed issues of fact." See also id. at 438 ("When a factual issue is disputed, oral testimony is preferable to affidavits.").

The District Court's ruling on the Lindberg and Atkinson affidavits was particularly appropriate given that the State had passed up several opportunities to present these witnesses' testimony in an appropriate fashion:

a). When the District Court held a Scheduling Conference on August 5, 1999, to decide whether to commence the preliminary injunction trial on September 22, 1999, as NEMA had requested, the State asked for additional time. With NEMA's explicit acquiescence, the District Court offered to postpone the trial to a later date, provided that the State would agree to postpone the requirement that lamp manufacturers submit a labeling plan by October 1, 1999. (Supplemental *78 JA730-37). The State refused this offer. *Id.* Any difficulty the State subsequently had in arranging for its witnesses to attend the September 22, 1999, trial was thus the direct consequence of its own actions.

- b). Once the District Court on August 5, 1999, set the September 22, 1999, trial date, the State had more than five weeks to preserve by deposition (including NEMA cross-examination) the testimony of any witness who would be unable to attend the trial. Because Lindberg and Atkinson reside more than 100 miles from the place of trial, any such deposition testimony could then have been read into the trial record, see Fed. R. Civ. P. 32(a)(3)(B). But the State made no effort to depose either witness.
- c). The District Court bent over backwards to accommodate the State. It permitted one of the State's other witnesses (Dr.Kieff) to testify during trial by video conference, even though the District Court indicated that the prerequisites probably were not satisfied (see Fed. R. Civ. P. 43(a)(permitting *79 testimony by video conference "for good cause shown in compelling circumstances"); JA338 (District Court: ("this doesn't seem to be a compelling circumstance."). But the State failed to arrange for Lindberg or Atkinson to testify by video conference.

Under these circumstances, the District Court was well within its discretion in declining to rely upon the Lindberg or Atkinson affidavits as they bore on contested facts, or to grant a continuance in the middle of the trial. See, e.g., Morris v. Slappy, 461 U.S. 1, 11 (1983) (The problem "of assembling the witnesses, lawyers, and jurors at the same place at the same time ... counsels against continuances except for compelling reasons."); see also Dow Chem. Pac. Ltd. v. Rascator Maritime S.A., 782 F.2d 329, 341-42 (2d Cir. 1986) (court acted within its discretion in denying request to reopen record to admit evidence from witness who had not attended trial due to "commitments in Europe during the time for which trial was scheduled" - *80 not a "compelling reason"). [FN19] Thus, even assuming (contrary to fact) that the Lindberg or Atkinson affidavits contain statements at odds with the District Court's relevant findings, [FN20] the Court acted properly to *81 exclude their testimony on contested facts. Accordingly, the State errs in citing the Lindberg affidavit repeatedly in its appellate brief as if it were in evidence. (See, e.g., Vt.Br. 5-6, 45).

FN19. The Court was equally correct to accept the brief but not the accompanying affidavits submitted by one of the amici, notwithstanding Vermont's unsupported contention to the contrary(see Vt.Br. 57-59).

FN20. In fact, Lindberg's affidavit does not contradict the District Court's findings that Vermont's labeling would not be effective and that, even if that were not the case, the labeling would only "address[] ... a very small portion of the problem of mercury entering the environment" because most of that is due to power plant emissions that occur outside of Vermont's borders. 72 F. Supp.2d at 454. Lindberg's affidavit never states that mercury-containing lamps emit a substantial portion of the mercury that is emitted into the environment anywhere, much less in Vermont. In fact, Lindberg states that, prior to the research that his affidavit describes, he had estimated that all of the mercury emitted from landfills in Florida - not only the mercury emitted from lamps but from all sources within Florida's landfills including large sources such as "batteries" (JA169) - was "<1% of the estimated total anthropogenic [i.e., human-made] Hg releases to air in the state [though] these sources may represent more significant fractions of the Hg burden in areas distant from major point sources such as power plants." (JA179-80). Although he states that his "estimate for landfill mercury emissions in Florida will increase" because one of the landfills he studied is not representative of others in Florida (JA180), he never states what the increase will be or what portion of total mercury emissions in Florida he will now estimate are attributable to mercury-containing lamp emissions.

Atkinson averred that "labels of some type can be affixed to mercury-containing lamps and the requirements of the Vermont statute are well within the bounds of existing technical feasibility." (JA155). Atkinson's claims about technical feasibility are immaterial, however, because "the issue is not whether NEMA members are able to label their products; the issue is, whether under the circumstances present in this case and consistent with the Constitution, the defendants can require them to label their products." 72 F. Supp.2d at 454.

B. The Erdheim Testimony Was Properly Admitted.

The State also argues that the District Court abused its discretion in permitting NEMA witness Erdheim to testify that U.S. EPA figures showed that the percentage of mercury emitted into the environment that is attributable to fluorescent lamps is approximately "half a percent." See Vt.Br. 51-52, 54-55 (citing JA361). While Vermont now pejoratively *82 characterizes Mr. Erdheim as a "lobbyist," the State acknowledged that the Governor of Vermont himself has appointed Mr. Erdheim to the Vermont Mercury Advisory Task Force. (JA317). Indeed, Mr. Erdheim was a peer reviewer of the Northeast States and Eatern Canadian Provinces Mercury Study; has testified before numerous state legislatures about mercury emissions and their regulation; and has extensive governmental experience in mercury regulatory issues. (JA315-18).

Moreover, Mr. Erdheim's testimony was essentially confirmed by one of the State's own mercury experts, who conceded that available numerical estimates suggested that about "half a percent" of the mercury being deposited in Vermont each year is attributable to mercury-containing lamps. (Tr.Vol. II 159-60). [FN21] Indeed, wholly uncontested facts confirm the correctness of the District Court's finding *83 (72 F. Supp.2d at 454) that the portion of mercury emissions that would be addressed by Vermont's lamp labeling requirements is "very small." [FN22]

FN21. This State witness stated that one of the components making up this "half a percent" figure had in his opinion been underestimated but he was not able to state by how much. (Tr.Vol. II 157-58).

FN22. The first uncontested fact is that the total amount of mercury contained in all of the 1.1 million lamps sold in Vermont each year is approximately 37 pounds, as testified to by NEMA witness Erdheim (JA362) and acknowledged by State expert Nierenberg (Tr.Vol. II 99). The second undisputed fact is that State expert Scherbatskoy himself "conservative[ly] estimate [d] "that the total amount of mercury deposited from all sources into Vermont each year is 2,289 pounds. (Tr.Vol. II 159). Thus, even if all of the mercury contained in the lamps sold in Vermont each year were emitted into the environment and deposited in Vermont (an unrealistic assumption, as Scherbatskoy himself testified (Tr.Vol. II 153-59)), it would account for only about 1.75% of total deposition (37 pounds out of 2,289 pounds) - a "very small portion."

C. The Crawford Testimony Was Properly Admitted.

The State incorrectly argues that the District Court abused its discretion in allowing General Electric's Product Manager for the North American Consumer Fluorescent Market to testify about the costs of compliance with Vermont's labeling requirements, using both General Electric's own exhaustively developed data^[FN23] and also survey data compiled by NEMA *84 from GE's competitors Philips Lighting and OSRAM-SYLYANIA. It would have unnecessarily extended the hearing for NEMA to have presented additional witnesses from Philips Lighting and OSRAM-SYLVANIA to discuss their precise costs of compliance, particularly when the State had a 6E witness available and did not ask him a single question about the amounts or items included in GE's own costs (Tr.Vol. I 138-53). The District Court ultimately did not rest its decision on a particular cost estimate, but rather on the fact that the costs of compliance with the Vermont labeling requirement would be substantial. *Cf. Raymond Motor Transp.* (Supreme Court strikes down Wisconsin regulation barring operation of 65-foot double trailers without deeming it necessary to determine with specificity the industry-wide costs of compliance and relying instead on testimony as to two companies' costs, 434 U.S. at 439 n.14).

FN23. Vermont purports to find the GE data unreliable (Vt.Br. 12 n.2), but in fact it was meticulously developed using both preexisting and newly derived data. (JA267-74).

*85 CONCLUSION

The District Court's order granting NEMA's motion for a preliminary injunction should be affirmed.

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION, Plaintiff F Appellee, v. William H. SORRELL, As Attorney General of the State of Vermont, John Kassel, Vermont Agency of Natural Resources, Defendants F Appellants.

2000 WL 33980809 (C.A.2) (Appellate Brief)

Briefs and Other Related Documents (Back to top)

- 2001 Wt 34093814 (Appellate Brief) Amici Curiae Brief of the National Association of Manufacturers and the Electronic Industries Alliance, in Support of Appellee National Electrical Manufacturers Association's Petition for Rehearing and Suggestion for Rehearing En Banc (Dec. 08, 2001) Original Image of this Document (PDF)
- 2001 WL 34711667 (Appellate Petition, Motion and Filing) Petition of Appellee National Electrical Manufacturers Association for Rehearing and Suggestion for Rehearing en Banc (Nov. 02, 2001) Original Image of this Document with Appendix (PDF)
- 2000 WL 33977195 (Appellate Brief) Reply Brief of Appellants Sorrell and Kassel (May. 17, 2000) Griginal Image of this Document (PDF)
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Briefs and Other Related Documents

United States Court of Appeals, Second Circuit. NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION, Plaintiff - Appellee,

William H. SORRELL, as Attorney General of the State of Vermont, John Kassel, as Secretary, Vermont Agency of Natural Resources, Defendants - Appellants.

CONSERVATION LAW FOUNDATION, INC., Vermont Public Interest Research Group, Vermont Natural Resources Council, Inc., National Wildlife Federation, Lake Champlain Committee, New Hampshire, State of New Hampshire Department of Environmental Services, Mercury Policy Project, Movants.

No. 99-9450. May 17, 2000.

On Appeal from the United States District Court for the District of Vermont

Reply Brief of Appellants Sorrell and Kassel

Ronald A. Shems, Rebecca Ellis, Dianne Sanford, Assistant Attorneys General, State of Vermont, Office of the Attorney General, 109 State Street, Montpelier, Vermont 05069-1001, (802) 828-3193.

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*1 I. INTRODUCTION

It is undisputed that mercury is extremely toxic and that Vermont is seeking to mitigate already widespread mercury contamination of the environment. Much of Vermont's mercury pollution originates from local sources such as the solid waste stream. Indeed, spent fluorescent light bulbs alone account for at least 21% of Vermont's in-state mercury emissions. Scherbatskoy Aff. ¶ 16.

By requiring labels on mercury-containing products sold in Vermont - labels that inform consumers that the product should not be thrown away - Vermont is addressing an important source of mercury pollution. Furthermore, Vermont is attacking the problem by regulating an activity that occurs wholly within its borders, i.e. the sale "in this state" of products that contain mercury. Vt. Stat. Ann. tit. 10, § 6621d(a).

NEMA claims that the Vermont market is too small, and that some of its members are too big to comply with Vermont law. NEMA Brief, 8. It asserts that the alleged inconvenience of its members' compliance gives rise to Commerce Clause and First Amendment violations.

NEMA's claims, however, raise very serious questions that its arguments utterly fail to address. For example, is a state's ability to exercise its police powers commensurate with its market share? Does a larger, global company have greater Commerce Clause and First Amendment rights than smaller. more adaptable *2 companies? Or alternatively, does the company with the highest costs and least flexibility set the bar for the industry-wide burden imposed by a state's non-discriminatory exercise of police powers?

NEMA's novel theories answer each of these questions with an unequivocal "yes." However, there is no basis either in law or the facts of this case to support NEMA's claimed rights. Indeed, NEMA's arguments effectively call for the revival of Lochner [FN1] era jurisprudence under the guise of Commerce Clause and First Amendment rights. Compare Grocery Mfrs. of America, Inc. v. Gerace, 755 F.2d 993, 1005 (2d Cir. 1985) (Commerce Clause precludes a court from substituting its judgment for that of the Legislature).

FN1. Lochner v. New York, 198 U.S. 45 (1905) (labor law violates company's substantive due process right to freely contract), overruled by Nebbia v. New York, 291 U.S. 502 (1934).

Instead, this case should be viewed for what it is: Vermont's rational and concededly non-discriminatory effort to address the serious problem of mercury pollution by regulating the in-state sale of products containing mercury.

II. NEMA'S STATEMENT OF FACTS IS SILENT ON CRITICAL ISSUES, BUT EXAGGERATES OTHER ISSUES.

A. Silence.

NEMA's statement of facts is striking in its silence on mercury's toxicity. NEMA does not dispute the fact that miniscule amounts of mercury can create severe public health and environmental problems. See, e.g., Tr.II: 116-118. Nor *3 does NEMA dispute that local sources are responsible for 60% of Vermont's mercury pollution and that fluorescent bulbs account for at least 21% of Vermont's in-state mercury emissions. JA 431-32. NEMA offered only national statistics. JA 52 ("Based on United States government studies, the disposal of mercury containing lamps accounts for a very small percentage of total domestic mercury emissions"). In short, no one disputes Vermont's significant interest in controlling in-state sources of mercury pollution.

Likewise, NEMA's factual statement is silent on the efficacy of labeling. NEMA stops well short of claiming that labels do not work. Instead, NEMA only asserts that its proposals would be "more effective." NEMA Brief, 4, 23.

There is good reason for NEMA's caution. NEMA does not dispute the well-established success of highly analogous bottle deposit labels, Tr.III: 163-64, and recycling labels on plastics, batteries, and other products, Tr.III: 141-45. Likewise, a blanket claim that labels are ineffective defies use of labels as the centerpiece of numerous state and federal programs regulating hazardous waste, toxic substances, pesticides, foods, drugs, and other products.

In fact, lamp manufacturers themselves rely on labels. Philips labels its low-mercury fluorescent lamps with the "ALTO" logo and explains on its packaging *4 that "ALTO" means low mercury and good for the environment. Vt. Exhibits. 1, 2; Tr.III: 169-172. Likewise, GE labels some of its so-called "low-mercury emission" fluorescent lamps with the "ECOLUX" logo. JA 40; Tr.I: 147-48. Consistent with standard business practice, Philips and GE adopted the ALTO and ECOLUX labels with confidence that such labels are an effective method of conveying the ALTO and ECOLUX messages. Tr. III: 170.

NEMA is also stone silent regarding its true motivation. NEMA couches this matter under the Commerce and Supremacy Clauses, and despite the coalition of States coordinating a consistent approach to mercury pollution, NEMA claims that future State laws may potentially conflict with Vermont's labeling requirement. The central fact of this matter, however, is that NEMA is opposed to all labeling whether on a State or a national level. [FN2] Tr.I: 233-35.

FN2. Federal legislation would obviate all of NEMA's claims here except, theoretically, its First Amendment claim.

B. Exaggeration.

In contrast, NEMA exaggerates the impacts and effects of labeling in several significant respects. First, NEMA claims that the "only way that manufacturers could comply with the State's labeling requirements would be to retool their manufacturing and packaging operations at each of the 60 worldwide plants" NEMA Brief, 15. NEMA further asserts that Vermont does not dispute this claim.

*5 Vermont does dispute this claim. [FN3] Fluorescent tubes and compact fluorescent bulbs constitute the vast majority of mercury-containing bulbs sold worldwide and in Vermont. Dr. Atkinson, the former Engineering Manager for Westinghouse's Lamp Divisions and a lecturer emeritus at California Polytechnic Institute stated, in his affidavit, that stickers could easily be developed to bring compact fluorescents and fluorescent tubes into compliance with the labeling requirement. JA 155. Use of

stickers avoids any change to the manufacturing process. *Id.* Indeed, manufacturers, distributors, *or* retailers could apply the stickers. Nothing in the record contradicts Dr. Atkinson's statements.

FN3. The District Court stayed discovery pending this appeal. Vermont will not concede any of NEMA's factual claims without having verified such claims through discovery.

Moreover, NEMA's broad-brush assertion defies common sense. On one hand, NEMA touts the different processes used by its members to manufacture the several different types of bulbs that they produce. See JA 275 (GE's competitors "definitely are using a different process than GE which is probably less costly to convert to comply with the Vermont Legislation."); NEMA Brief, 9 ("Lamp manufacturers make a tremendous variety of lamps"). On the other hand, NEMA asserts that to retool each plant is "the only way" to comply. Certainly, the variety of lamps and processes gives rise to more than one method of compliance.

*6 In any event, what NEMA characterizes as "retooling" is not an onerous process. It is a simple and routine matter of changing an ink pad. JA 154-55. Indeed, it is well known that lamp manufacturers regularly produce runs of lamps with specialty retail labels. There is little difference between changing an ink pad to manufacture a profitable run of lamps under the "ACE Hardware" label, and changing an ink pad to manufacture bulbs that comply with Vermont's labeling requirement. *Id.*

Likewise, labeling high intensity discharge (HID) lamps - the third type of mercury-containing lamp sold in Vermont - is easy and inexpensive. Nonetheless, NEMA vigorously claimed that it is physically impossible to label HID lamps. Tr.III: 25-27, 35-36. NEMA was so adamant in this claim that, based on NEMA's representations, Vermont was preparing to exempt HID lamps from the labeling requirement. *Id.* But at that time, and apparently unbeknownst to NEMA, one of its members (who manufactures bulbs in China) started to label HID bulbs in full compliance with Vermont law. *Id.*; Vt. Exhibits 23-25. Only when faced with the truth, did NEMA concede that the HID lamps could, in fact, be easily and inexpensively labeled. Tr.I: 134-35.

Second, with no more evidence than the opinion offered by its lobbyist, JA 383, NEMA asserts that lamp labels, regardless of their content, will confuse consumers. NEMA Brief, 22-23. Indeed, NEMA goes so far as to claim that any *7 Vermont label would be an "outright deception" to consumers. *Id.* at 23. NEMA's paternalistic claim not only demeans the average consumer's intelligence, but again defies common sense. Residents of New Hampshire, a state without a bottle bill, are not confused when they buy beverages in containers labeled "VT 5¢." *See* Tr.III: 163-64. Nor are Vermonters confused when they purchase paint thinner labeled with California's Proposition 65 warning or New Jersey's right to know information. Tr.III: 137-146.

Third, again armed with nothing more than the opinion offered by its lobbyist, a non-practicing lawyer, NEMA claims that any lamp label would "run counter to the legal requirements of the federal government and the other states." NEMA Brief, 21-22. [FN4] NEMA specifically asserts that a Vermont label on a bulb sold in Minnesota allows a Minnesotan to "reasonably assume ... that they can place lamps in the trash everywhere except Vermont" when such behavior is prohibited in Minnesota. However, Minnesota does not share NEMA's concerns. To the contrary, as evidenced by its *amicus curiae* participation in this matter, Minnesota (and the several other *amici* States) supports Vermont's labeling effort and affirmatively stated that Vermont's labeling requirement "is entirely *8 consistent" with its efforts. *Amicus* Brief, 16-17. Indeed, the several States believe that the impact of Vermont's program would enhance individual state mercury control efforts. *See, e.g.*, JA 143.

FN4. NEMA makes the legal argument that any Vermont label would violate Federal Trade Commission Rules governing environmental marketing claims, 16 C.F.R. § 260.7(d). The consumer information provided by the Vermont label is, by no stretch of the imagination, such a marketing claim.

NEMA also overstates the potential liability for labeling law violations. NEMA states only that "violation of this statute is punishable by a criminal penalty," NEMA Brief, 10-11, despite its full knowledge of

the far more commonplace voluntary, administrative, and civil remedies available to enforce this law. See Vt. Stat. Ann. tit. 10, Ch. 201; Tr.I: 62.

III. NEMA CANNOT RECONCILE ITS THEORY OF IRREPARABLE HARM WITH ESTABLISHED STANDARDS GOVERNING PRELIMINARY INJUNCTIONS. A. NEMA fails to make a clear showing of irreparable harm.

NEMA continues to assert that compliance costs and sovereign immunity - and nothing more constitute irreparable harm. "Irreparable harm is thus established in this case, because the State of Vermont's lamp and package labeling requirements would inflict monetary harm on manufacturers for which the state could not be required to answer in damages." NEMA Brief, 36. However, NEMA fails to adequately address the several significant shortcomings of its formulation of irreparable harm.

First, NEMA attempts to dismiss the several in-depth appellate opinions rejecting this formulation of irreparable harm by remarking that "only two of [the *9 opinions] even involved the Eleventh Amendment." Id. at 40 n.7. What NEMA does not say is that every one of those cases involved sovereign immunity. See Hoxworth v. Binder Robinson & Co., 903 F.2d 186, 206 (3d Cir. 1990); Wisconsin Gas Co. v. Federal Energy Regulatory Comm'n, 758 F.2d 669, 674 (D.C. Cir. 1985); American Hospital Ass'n v. Harris, 625 F.2d 1328, 1331 (7th Cir. 1980); A.O. Smith Corp. v. Federal Trade Comm'n, 530 F.2d 515 (3d Cir. 1976); Virginia Petroleum Jobbers Ass'n v. Federal Power Comm'n, 259 F.2d 921, 925 (D.C. Cir. 1958). The Eleventh Amendment merely reflects the notion that States are entities with sovereign immunity. Alden v. Maine, 527 U.S. 706, 119 S. Ct. 2240, 2246-47 (1999).

Second, NEMA fails to reconcile its simplistic formulation of irreparable harm with the well-established rule that irreparable harm cannot be speculative. See Tom Doherty Assocs. v. Saban Entertainment, 60 F.3d 27, 38 (2d Cir. 1995). Rather, NEMA attempts to mask the speculative nature of its claimed injury.

In apparent recognition of the fact that the District Court relied on erroneous cost figures, see Vermont Brief, 34-35, NEMA argues that "it is not necessary to credit any particular cost estimate" because the District Court found that such costs would be "substantial." NEMA Brief, 18. Indeed, in an argument that highlights the speculative nature of the District Court's conclusions, NEMA goes so far as to *10 assert that the District Court concluded that costs would be "substantial" without resting its decision on any particular cost estimate. Id. at 84.

As NEMA now concedes, its purported harm cannot be quantified. Therefore, NEMA must be held to a "clear showing" standard in meeting its burden of proof that it will suffer actual and imminent irreparable injury. Tom Doherty Assocs., 60 F.3d at 38. "A 'clear showing' standard incorporates the primary requirements of irreparable injury because it assures that the harm - although not quantifiable - is not speculative. We expect the 'clear showing' standard to be infrequently met" Id.

NEMA failed to meet the clear showing standard. [FN5] Absent valid cost estimates, there was no evidence to support the District Court's conclusion that costs would be "substantial." Rather, the record merely reflects the facts that GE has substantially higher costs and significantly less flexibility than its large competitors, JA 275; Lesser Aff. ¶¶ 30-32 (document 25), and that smaller companies such as Eye Lighting are, in fact, willing and able to comply, Tr.III: 25. Only by engaging in speculation can one translate GE's problems into an industry-wide burden.

FN5. The District Court, despite its inability to quantify the alleged harm, did not even attempt to apply the clear showing standard.

Moreover, the District Court found that NEMA's members would not bear compliance costs, but instead that they "would be passed onto consumers, possibly *11 raising the price of already more expensive mercury containing lamps." JA 597. NEMA responds to this finding by asserting that the District Court was merely speculating. NEMA Brief, 41. However, both NEMA and Vermont presented substantial evidence relating to the alleged incremental per lamp cost increase resulting from labeling. JA 58, 160, 283; Exhibit 28A ("Cost of SKU'S") (Confidential Materials).

NEMA further attempts to avoid this finding's impact by citing cases that supposedly recognize "the 'economic truth' that passing on costs, *i.e.* increasing prices, will cause a reduction in product demand and therefore cause injury to the manufacturer." NEMA Brief, 41. However, truth - economic or otherwise - is established in the courts by the presentation of evidence. NEMA presented no evidence whatsoever of any purported harm to manufacturers resulting from any price increase.

Further, few claims are more speculative than a lawyer's assertion that cases addressing other products governed by other regulatory programs establish the "economic truth" of bulb labeling. Indeed, only an expert economist could offer an opinion as to whether lamps - products whose sales are promoted and subsidized by the Federal and Vermont governments, Tr.I: 120; Tr.III: 119-124 - would suffer *12 from a price increase (using NEMA's own figures) of \$0.0007 per lamp. JA 159-160 (NEMA's one-time costs amortized over the expected five year life of a lamp).

As a practical matter, one can hardly conclude NEMA has met the clear showing standard when its evidence results not only in a finding that its members will not bear the alleged irreparable harm, but also in a confusing presentation resulting in the District Court's reliance on concededly erroneous cost figures.

Third, NEMA answers Vermont's argument that NEMA's claim of irreparable harm renders the irreparable harm element meaningless whenever one seeks to enjoin government action by asserting that "this overlooks the fact that this Court requires" a heightened showing on the merits in such cases. NEMA Brief, 42 n.9, citing <u>International Dairy Foods Ass'n v. Amestoy</u>, 92 F.3d 67, 70 (2d Cir. 1996) (" *IDFA*"). What NEMA overlooks is that this Court did not create this heightened standard as a substitute for the irreparable harm element. Rather, this heightened standard must be met *in addition to* meaningful application of the traditional irreparable harm element. Otherwise, this Court's policy goal of protecting "government action taken in the public interest" would not be achieved. <u>IDFA</u>, 92 F.3d at 70; see also <u>Able v. United States</u>, 44 F.3d 128, 131-32 (2d Cir. 1995).

*13 B. NEMA does not suffer irreparable harm under the First Amendment by merely asserting a First Amendment violation.

NEMA asserts that irreparable harm "is necessarily satisfied when a First Amendment violation is asserted." NEMA Brief, 44. If this were correct, then every plaintiff would assert a First Amendment violation, because the mere assertion of a violation, whether frivolous or not, would establish the irreparable harm prerequisite for a preliminary injunction. NEMA's theory clearly leads to ridiculous results. This is particularly true in a case such as this one, where the Plaintiff does not challenge the content of the message to be communicated.

Unlike the plaintiff in *IDFA*, NEMA members are not being forced to express a view contrary to their own. NEMA does not object to conveying the statute's message via shelf placards, product invoices, or information sheets. NEMA Brief, 13-14. It objects only to the means of communication, product labels. This alleged harm does not abridge plaintiff's First Amendment rights. *Compare United States v. Frame*, 885 F.2d 1119, 1132-33 (3d Cir. 1989) (beef producers were required to fund commercial message to which they did not necessarily subscribe).

NEMA has failed to allege any harm - and certainly not an irreparable harm - under the First Amendment. In a case on point, the Supreme Court found that mandatory assessments imposed on fruit growers to pay for a generic advertising campaign did not implicate any rights under the First Amendment. *14 Glickman v. Wileman Brothers, 521 U.S. 457, 469 (1997). Like NEMA's lamp manufacturers, the fruit growers in Wileman Brothers were not being compelled to express a view contrary to their own, or to endorse any political or ideological views. Id. The fact that fruit growers

"might earn more money in an unregulated market ... provide[s] no basis for concluding that factually accurate advertising constitutes an abridgement of anybody's right to speak freely." *Id.* at 474. Having found no harm under the First Amendment, the Court analyzed, and then rejected, the fruit growers' claim under the Commerce Clause. *Id.* at 476.

Preliminary injunctions are an extraordinary form of relief. The mere assertion of a First Amendment violation, bereft of any demonstration of harm, does not entitle NEMA to this extraordinary remedy.

IV. Commerce Clause

A. In passing the Resource Conservation and Recovery Act (RCRA), Congress clearly authorized state programs that would have an effect on interstate commerce.

NEMA's discussion of federal law disregards the obvious: Congress specifically contemplated that States would adopt controls over hazardous waste and hazardous products, and that such controls might have an effect on interstate commerce. NEMA Brief, 65-70.

Pursuant to the Resource Conservation and Recovery Act (RCRA), the Environmental Protection Agency requires handlers of hazardous waste to label *15 spent fluorescent lamps and containers holding spent fluorescent lamps. 40 C.F.R. §§ 273.14(e) & 273.34(e) (fluorescent lamp or container holding fluorescent lamp must be clearly marked with one of the following phrases: "Universal Waste - Lamp(s)," or "Used Lamp(s)"). Under RCRA, States may adopt their own controls over hazardous wastes and products, including labels on fluorescent lamps, so long as the state-enacted requirements are "more stringent than those imposed" by federal regulations. 42 U.S.C. § 6929 (RCRA); see also 15 U.S.C. § 2617(a)(1) & (2) (Toxic Substances Control Act) ("TSCA"); Old Bridge Chemicals, Inc. v. New Jersey Dep't of Environmental Protection, 965 F.2d 1287, 1296-97 (3d Cir.) (New Jersey's labeling requirement for hazardous wastes is expressly provided for by RCRA), cert. denied, 506 U.S. 1000 (1992).

In passing RCRA, Congress clearly contemplated that States would enact controls over hazardous wastes and products, even though the state-enacted programs might have incidental effects on interstate commerce. *Environmental Technology Council v. Sierra Club*, 98 F.3d 774 (4th Cir. 1996), cert. denied, 521 U.S. 1003 (1997), a case cited by NEMA, is consistent with Vermont's position. As recognized in *Environmental Technology Council*, RCRA does not authorize States to discriminate against out-of-state interests in favor of in-state interests. *Id.* at 785-86 (striking down North Carolina law that facially discriminated against *16 out-of-state hazardous waste). On the other hand, RCRA does authorize state programs that have an even-handed effect on interstate commerce, so long as the effect is not "unreasonabl[e]." 40 C.F.R. § 271.4 ("To obtain approval, a State program must be consistent with the Federal program and State programs applicable in other States").

NEMA also argues that Congressional authorization was not raised below and cannot be considered on appeal. In fact, both NEMA and the State raised the issue below. NEMA put the issue in play by claiming that RCRA preempts Vermont's labeling law. See NEMA's Memorandum in Support of Motion for Preliminary Injunction, 34 (document 3). In response, the State of Vermont asserted that RCRA "authoriz[es] States to impose more stringent requirements on the management of spent fluorescent lamps." Vermont's Memorandum in Opposition to Motion for Preliminary Injunction, 3 & 37-39 (document 16). This Court is fully justified in taking up the issue on appeal.

B. NEMA's far-fetched attempt to analogize the Connecticut price-affirmation statute struck down in *Healy* with Vermont's labeling statute is simply not credible.

NEMA's primary Commerce Clause argument is that Vermont's labeling law directly regulates out-of-state transactions. NEMA Brief, 48. This claim is based on the argument that Vermont's law conflicts with other states' regulations. Under no reasonable interpretation does the Vermont statute regulate activities *17 outside of the State, or conflict with other states' regulations. See Vt. Stat. Ann. tit. 10, § 6621d(a) (Vermont's labeling law applies only to mercury-containing products sold in Vermont).

To support its contention, NEMA struggles mightily to liken Vermont's statute to the Connecticut price-affirmation statute struck down in *Healy v. The Beer Institute*, 491 U.S. 324 (1989), a case wholly dissimilar to the case at hand. To begin, the Connecticut statute "on its face" discriminated against interstate commerce. 491 U.S. at 340. "By its plain terms, the Connecticut affirmation statute applies solely to interstate brewers or shippers of beer, that is, either Connecticut brewers who sell both in Connecticut and in at least one border State or out-of-state shippers who sell both in Connecticut and in at least one border State." *Id.* at 341. In contrast, Vermont's law is neutral both on its face and in effect, a fact conceded by NEMA.

In addition, the Connecticut statute had a *direct* effect on the prices at which liquor could be sold in other states. <u>491 U.S. at 337-38.</u> The Connecticut statute's direct effects on interstate commerce were due to the complicated and interlocking nature of price-affirmation statutes in Connecticut and surrounding states. *Id.* at 338. In contrast, the incidental effects of Vermont's statute on interstate commerce, if any, are entirely consistent with other states' attempts to reduce mercury emissions. *See infra*, p. 18.

- *18 NEMA's approach to Commerce Clause analysis would lead to absurd results. Almost all state public health statutes have some impact on interstate commerce; that does not mean that all state public health statutes violate the Commerce Clause in the same way as the price-affirmation statute in *Healy*. Like Vermont's bottle deposit law, Vermont's mercury-labeling law is a clear, simple and constitutional approach to solving an important environmental problem. See Vt. Stat. Ann. tit. 10, § 1524 (requiring 5¢ deposit label on bottles).
- C. Vermont's statute is consistent with other States' attempts to regulate mercury-containing products within their borders.

Despite the affidavits and memoranda of other States in support of Vermont's labeling statute, NEMA baldly asserts that Vermont's statute is "interfering with the abilities of other states to regulate within their borders." NEMA Brief, 51. As NEMA itself acknowledges, however, no other State in the country currently requires labeling of mercury-containing lamps. *Id.* at 28-30. As a result, there is no possibility of actual conflict between Vermont's statute and the statutes of other States, nor is there any evidence of potential conflict. Indeed, NEMA does not cite, much less analyze, a single state statute or rule with which Vermont law would conflict.

To the contrary, the record is replete with affidavits and memoranda of other States affirming that Vermont's labeling statute is consistent with the efforts of other States to reduce mercury emissions:

*19 Vermont's law is entirely consistent with the legislative proposals being considered in other States. Indeed, the adoption of legislation similar to Vermont's law by other States will provide greater opportunities for interstate partnerships with respect to the recycling and disposal of mercury. Such interstate partnerships are envisioned and encouraged by RCRA.

Amicus Brief, 15-16; see also JA 143 (Affidavit of John James, Department of Environmental Protection, State of Maine); JA 148 (Affidavit of Richard Barlow, Department of Environmental Protection, State of Connecticut); JA 153 (Affidavit of Stephanie D'Agostino, Department of Environmental Services, State of New Hampshire). These statements stand unrebutted.

D. Commerce Clause analysis precludes the Judiciary from substituting its judgment for that of the Legislature.

NEMA invites this Court to revive *Lochner*-era jurisprudence by engaging in an evaluation of the pros and cons of product labels compared to shelf placards. NEMA Brief, 26-28. The Courts have consistently rejected a substantive due process approach to Commerce Clause analysis. *See, e.g., K-S Pharmacies, Inc. v. American Home Products Corp., 962 F.2d 728, 731 (7th Cir. 1992) ("The dormant commerce clause does not call for proof of a law's benefits, after the fashion of substantive due process, whenever the subject is trade.").*

Faced with a battle of the experts, the Court's mandate is to determine "whether the means of regulation chosen are reasonably adapted to the end *20 sought." South Carolina Highway Dep't v. Barnwell Bros., Inc., 303 U.S. 177, 190 (1938). Accord Bibb v. Navajo Freight Lines, Inc., 359 U.S. 520, 530 (1959) (Harlan, J., concurring) (invalidating Illinois statute requiring trucks to use contour mud flaps, where the contour mud flap "possesse[d] no advantages' in terms of safety over the conventional flap permitted in all other States, and indeed create[d] certain safety hazards."); Association of Int'l Auto. Mfrs., Inc., v. Abrams, 84 F.3d 602, 613 (2d Cir. 1996) (reversing the grant of summary judgment and remanding for further factual development to determine the reasonableness of the New York Legislature's conclusion that stronger vehicle bumpers would be associated with lower insurance premiums).

The State presented substantial testimony establishing the reasonableness of Vermont's labeling law and the efficacy of product labels. See Tr.III: 164 (Heffernan Testimony); Tr.III: 141 (High Testimony); Tr.II: 186-88 (Kieff Testimony). Engaging in a comparison of the pros and cons of one alternative versus another would be an inappropriate descent into the realm of substantive due process.

*21 E. The benefits of Vermont's law, which include reduced risks to human health and the environment, justify the alleged costs of compliance.

Mercury is hazardous to human health and the environment. This is a basic, undisputed fact that NEMA conveniently avoids in its discussion of the balancing test under Pike v. Bruce Church, Inc., 397 U.S. 137 (1970). NEMA Brief, 54-62.

Mercury is not, for example, like the mud flaps on a truck. NEMA Brief, 56 (citing Bibb v. Navajo Freight Lines, Inc., 359 U.S. 520 (1959) (striking down an Illinois statute that required a certain type of mud flap)). Nor is mercury anything like a 65-foot double trailer on a highway. NEMA Brief, 57 (citing Raymond Motor Transp., Inc. v. Rice, 434 U.S. 429 (1978) (striking down Wisconsin statute that barred trailers longer than 55 feet)). In both of those cases, the State failed to make a showing that the regulated product posed a danger to human safety. Bibb, 359 U.S. at 530; Raymond Motor, 434 U.S. at 448. In contrast, mercury is a known toxin, which can cause brain damage at extremely low levels of exposure.

The Supreme Court has often recognized the impropriety of weighing public health benefits of a nondiscriminatory statute against the costs of compliance. See, e.g., Brotherhood of Locomotive Firemen & Enginemen v. Chicago Rock Island & Pacific Railroad Co., 393 U.S. 129, 139-40 (1968). In Brotherhood, the Supreme Court reversed the district court and held that Arkansas' full-crew railroad statutes did not violate the Commerce Clause. "We think it plain that in *22 striking down the fullcrew laws ..., the District Court indulged in a legislative judgment wholly beyond its limited authority to review state legislation under the Commerce Clause.... A brief summary of some of the findings ... should suffice to show that the question of safety is clearly one for legislative determination." Id. at 136-37. Likewise, the intangible benefits of reduced exposure to mercury cannot be compared with the costs of labeling lamps. The question of acceptable risk is a legislative determination, not a judicial one.

Indeed, no balancing is even necessary once the Court has determined that the state law has only incidental effects on interstate commerce, and those effects are nondiscriminatory. See, e.a., Pacific Northwest Venison Producers v. Smitch, 20 F.3d 1008, 1016 (9th Cir. 1994); Old Bridge Chemicals. 965 F.2d at 1295 (only discriminatory burdens are considered in balancing test); K-S Pharmacies, Inc. v. American Home Products Corp., 962 F.2d at 731. Accord New York State Trawlers Assoc. v. Jorling, 16 F.3d 1303, 1307 (2d Cir. 1994) ("Provided a state does not discriminate against nonresidents ... it may impose incidental burdens on interstate commerce when exercising its police power to promote safety or general welfare."); Barringer v. Griffes, 1 F.3d 1331, 1338 (2d Cir. 1993) ('The Supreme Court has held repeatedly that 'the Commerce Clause prohibits economic protectionism - that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors."") (quoting *23 New Energy Co. of Indiana v. Limbach, 486 U.S. <u>269, 273 (1988)</u>). But see NEMA Brief, 65 (collecting cases). The purpose of the Commerce Clause is to prevent states from passing laws that discriminate against out-of-state interests; nondiscriminatory statutes with incidental effects on interstate commerce, such as Vermont's labeling law, are not subject to the same degree of scrutiny as protectionist statutes.

The benefits of Vermont's law, which include reduced risks to human health and an environment free of mercury, far outweigh the incidental costs of labels. Vermont's statute is fully compatible with the requirements of the Commerce Clause and should be held constitutional.

V. FIRST AMENDMENT

A. NEMA urges this Court to ignore controlling Supreme Court precedent on compelled commercial speech.

NEMA asks the Court to disregard the Supreme Court's test for commercially compelled speech, set forth in <u>Zauderer v. Office of Disciplinary Counsel</u>, 471 U.S. 626, 651 (1985), and to apply instead the Supreme Court's standard for restrictions on commercial speech, laid out in <u>Central Hudson Gas & Electric Corporation. v. Public Service Commission of New York</u>, 447 U.S. 557, 566 (1980). NEMA Brief, 71-72.

Zauderer provides the correct test for analyzing Vermont's law. Like the disciplinary rule upheld in Zauderer, Vermont's mercury labeling statute requires manufacturers to provide consumers with useful, factual information. *24 471 U.S. at 651 (upholding requirement that attorneys include cost and fee information in their advertising). Analyzing the regulation in Zauderer, the Supreme Court applied a "reasonably related" test, rather than Central Hudson's intermediate scrutiny standard, because a person's "constitutionally protected interest in not providing any particular factual information in ... advertising is minimal." Id. at 651. This is true irrespective of the State's purpose in compelling information. As explained in Zauderer:

Because the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed, we do not think it appropriate to strike down such requirements merely because other possible means by which the States might achieve its purposes can be hypothesized.... As a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied. The right of a commercial speaker not to divulge accurate information regarding his services is not such a fundamental right.

471 U.S. 651 n.14.

Like any other commercial entity, lamp manufacturers have only a minimal First Amendment interest in not divulging truthful information. As a result, *Zauderer* - not *Central Hudson* - provides the correct test for analyzing the statute's constitutionality.

Even applying *Central Hudson*, Vermont's mercury-labeling statute still survives constitutional scrutiny. As the district court has already recognized, "the *25 state has a substantial interest in protecting the health and safety of its citizens and environment by reducing mercury emissions." *National Electrical Manufacturers Assoc. v. Sorrell*, 72 F. Supp. 449, 456 (D.Vt. 1999). Under a different set of facts, this Court struck down Vermont's bovine-growth-hormone statute because satisfying "consumer curiosity" did not constitute a substantial state interest. *IDFA*, 92 F.3d at 74. "Absent ... some indication that this information [relating to the use of bovine growth hormone] bears on a reasonable concern for human health or safety or some other sufficiently substantial concern, the manufacturers cannot be compelled to disclose it." *Id.* at 74. The State's strong interest in reducing mercury emissions makes this case wholly distinguishable from *IDFA* and easily satisfies the substantial-interest prong of the four-part *Central Hudson* test.

B. The "Hg-in-a-circle" proposal is a red herring. This Court must determine the constitutionality of Vermont's statute, not a moot proposal set forth by the Agency of Natural Resources.

NEMA's single-minded obsession with the "Hq-in-a-circle" label is a classic red herring. NEMA Brief, 14, 15, 20, 24-26. Not surprisingly, NEMA's entire First Amendment argument relies on this hypothetical label. Take away this false assumption, and NEMA's argument falls apart.

NEMA misleads the Court when it says that Vermont's Agency of Natural Resources "demanded" that manufacturers label mercury-containing lamps with Hg in a circle. NEMA Brief, 14. As the record clearly indicates, the Agency *26 offered the Hq-proposal as a good-faith effort to compromise. JA 91 (Erdheim Aff. Ex. 6, Letter from Secretary Kassell dated June 16, 1999, page 3). "Hg-in-a-circle" died as a viable option when NEMA rejected the Agency's offer.

The issue in this case is not the appropriateness of the "Hg" proposal, but whether the agency can require any labeling at all. Evaluating a moot proposal to determine the constitutionality of Vermont's labeling statute misses the point entirely.

VI. NEMA'S TECHNICAL CLAIMS ATTEMPTING TO JUSTIFY THE DISTRICT COURT'S SEVERAL ERRORS ONLY HIGHLIGHT THE DISTRICT COURT'S RELIANCE ON FAULTY EVIDENCE AND THE FUNDAMENTAL WEAKNESSES OF NEMA'S CLAIMS.

A. NEMA's argument that the District Court properly excluded Vermont's affidavits is without merit.

NEMA argues that Vermont's witness affidavits were properly excluded because Vermont should have acceded to NEMA's demanded injunction during the August 5, 1999 scheduling conference if some of its witnesses would not be available. NEMA Brief, 77; SJA 731 (Transcript of Aug. 5, 1999 Conference). Vermont was served less than a week prior to this conference, and as clearly stated in the conference transcript, Vermont had not yet had a reasonable opportunity to hire experts, much less obtain their schedules. [FN6]

FN6. Acceding to NEMA's requested injunction would reward last-minute tactics. NEMA chose to file this broad and complex suit when it would be virtually impossible for the State to hire and prepare experts prior to the law's effective date. Moreover, the Vermont Legislature enacted a law that Vermont, in good faith, believes to be legitimate. Vermont can hardly be faulted for according proper respect to an Act of the Vermont Legislature.

*27 In any event, Vermont agreed to extend NEMA's time for compliance. Tr.I: 241-42; Tr.III: 4-6. Vermont's agreement was premised on the specific understanding that the opportunity to present live testimony would be allowed. Tr.I: 241-42; Tr.III: 4-5. Therefore, there is no merit to NEMA's argument.

NEMA also asserts that the unavailable witnesses could have been deposed prior to the hearing. This argument ignores several realities. First, it is standard practice to rely on affidavits in preliminary injunction hearings. Second, it would have required uncanny prescience to anticipate that affidavits would be excluded because the court would permit a lay witness to create legitimate factual issues by offering opinions that contradict those of qualified expert witnesses. See Vermont Brief, 50-59.

Third, the witnesses' affidavits were exchanged in lieu of discovery. Indeed, the witnesses' testimony was limited to the topics addressed in their affidavits. Scheduling Order (document 8), Depositions would have been viewed as superfluous and unnecessary, especially in light of the fact that the parties would have had to fly to California, Tennessee and the several amici States in the days *28 before the hearing. In short, NEMA's current argument notwithstanding, it is difficult to believe that NEMA would have agreed to such depositions.

NEMA also argues that Vermont should have provided these witnesses' testimony by videoconference. NEMA Brief, 78-79. NEMA's argument is, to say the least, surprising given its vigorous objections to the use of video conferencing for Dr. Keefe's testimony. Tr. I: 180. In any event, NEMA's argument is based on its unfounded assumption that Vermont arranged for one witness to appear by videoconference, but did not attempt to have other unavailable witnesses appear the same way.

B. NEMA fails to justify its lay witness's scientific opinions.

NEMA argues that it was appropriate for its lobbyist, Eric Erdheim - a non-practicing lawyer who has no scientific education or training - to offer expert scientific opinions. NEMA seeks to belatedly qualify him as a scientific expert by asserting that he was appointed to the Vermont Mercury Advisory Task Force. NEMA Brief, 82. This task force is a representative entity composed of scientists, politicians, an industry representative, a member of the Abenaki Self-Help Association, and the Secretary of the Agency of Natural Resources. Vt. Stat. Ann. tit. 10, § 6621e. His appointment as the industry representative to this task force does not qualify him as a scientific expert.

*29 In any event, the lobbyist offered an opinion limited to national mercury emission statistics. JA 52. He presented no evidence whatsoever on mercury in Vermont. These national statistics do not accurately reflect Vermont's situation. Vermont is a rural state without the coal-burning power plants and medical waste incinerators that drive national statistics. Tr.III: 13. Dr. Scherbatskoy, one of Vermont's scientific experts, testified that local sources such as landfills are responsible for 60% of Vermont's mercury pollution and that mercury from spent lamps is responsible for at least 21% of Vermont's in-state mercury emissions. JA 431-432. Dr. Scherbatskoy further stated that, based on developing research, his figures significantly *underestimate* the amount of mercury emissions from lamps.

NEMA offered nothing to dispute these figures - figures pertinent to Vermont's significant interest in controlling in-state sources of mercury pollution. Instead, NEMA makes the curious argument that Dr. Scherbatskoy effectively confirmed the lobbyist's scientific opinion because Scherbatskoy "was not able to state" the extent of the lobbyist's underestimation of mercury pollution caused by lamps. NEMA Brief, 82 n.21. Dr. Scherbatskoy, who ironically is one of the *scientists* appointed to the Vermont Mercury Advisory Task Force, was fully prepared to explain the research he relied on to determine that his figures *30 underestimate the extent of mercury pollution from lamps. [FN7] Adding to the irony, NEMA's lobbyist's utter lack of scientific education and training rendered him wholly unable to explain his opinions, thus depriving Vermont of any ability to challenge the merits of his opinions. NEMA's disingenuous argument is without merit.

FN7. NEMA objected and the District Court precluded this testimony. See Vermont Brief, 53.

C. The presentation of cost data by a witness with no personal knowledge of such data is hearsay and deprived Vermont of its right to challenge NEMA's claimed injury.

GE's assertion of its competitors' cost figures was hearsay. See Vermont Brief, 59-60. NEMA does not claim otherwise, nor does NEMA take issue with the fact Vermont was deprived of the right to cross examine a witness with personal knowledge of Philips' and OSRAM-Sylvania's cost estimates. Rather, NEMA makes the circular argument that "the District Court ultimately did not rest its decision on a particular cost estimate, but rather on the fact that the costs of compliance with the Vermont labeling requirement would be substantial." NEMA Brief, 84. [FN8] Clearly, however, the District Court relied on cost estimates (albeit incorrect cost estimates, see Vermont Brief, 34-35) to determine that such costs *31 would be substantial. Otherwise, there would have been no evidence whatsoever on which to base such a conclusion.

FN8. NEMA cites <u>Raymond Motor Transport</u>, 434 U.S. at 439 n.14, for the proposition that a court may find a burden on interstate commerce without specific industry-wide cost figures. NEMA Brief, 84. As explained on pages 35-37 of Vermont's Main Brief, <u>Raymond Motor Transport</u> turned on the fact that interstate transportation of goods was impeded. This impact is not present here.

Finally, NEMA argues that its hearsay testimony was justified because "it would have unnecessarily extended the hearing for NEMA to have presented additional witnesses from Philips Lighting and OSRAM Sylvania to discuss their precise costs of compliance." NEMA Brief, 84. However, compliance

with Vermont's due process rights is necessary. <u>Schulz v. Williams</u>, 38 F.3d 657, 658 (2d Cir. 1994) (defendant has absolute right to challenge evidence presented in support of preliminary injunction); <u>SEC v. Frank</u>, 388 F.2d 486, 491-93 (2d Cir. 1968) (same). Moreover, NEMA must be held to its burden of proof in its attempt to derail a program that protects the public health and environment from the undisputedly deleterious effects of mercury pollution.

*32 VII. CONCLUSION.

The District Court's decision should be reversed and the preliminary injunction vacated.

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION, Plaintiff - Appellee, v. William H. SORRELL, as Attorney General of the State of Vermont, John Kassel, as Secretary, Vermont Agency of Natural Resources, Defendants - Appellants. CONSERVATION LAW FOUNDATION, INC., Vermont Public Interest Research Group, Vermont Natural Resources Council, Inc., National Wildlife Federation, Lake Champlain Committee, New Hampshire, State of New Hampshire Department of Environmental 2000 WL 33977195 (C.A.2) (Appellate Brief)

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